D. D. N. J., F. D. C. 601–655 Issued February, 1943

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

601–655

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

WATSON B. MILLER, *Acting Administrator, Federal Security Agency.*

Washington, D. C., November 11, 1942.

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DRUGS SEIZED BECAUSE OF POTENTIAL DANGER TO HEALTH WHEN USED ACCORDING TO DIRECTIONS

601. Adulteration and misbranding of Bromo-Caps; misbranding of Rx S368957 Filled Capsules. U. S. v. 5 Drums of Rx 368957 Filled Capsules and 111 Display Cards and 214 Cartons of Bromo-Caps. Default decree of condemnation and destruction. (F. D. C. Nos. 4900 to 4902, incl. Sample Nos. 50246–E, 50247–E.)

This case was based on the interstate shipment of a quantity of acetanilid, aspirin, and caffeine capsules in drums, a portion of which had been repackaged and labeled "Original and Genuine Bromo-Caps." The repackaged capsules would have been dangerous to health when used according to the directions on the carton. The labeling of the repackaged capsules also overstated the acetanilid content by approximately 50 percent and it bore false and misleading claims. The labeling of both bulk and repackaged capsules failed to bear adequate directions for use and warning and satisfactory ingredient statements.

On June 13, 1941, the United States attorney for the District of Maryland filed a libel against 5 drums containing a total of 31,800 Rx S368957 Filled Capsules; and 111 display cards each containing 24 4-capsule-sized cartons and 2 12-capsule-sized cartons, and 202 4-capsule-sized cartons and 12 12-capsule-sized cartons of Bromo-Caps at Baltimore, Md., alleging that the articles had been shipped on or about April 11, 1941, by Parke, Davis & Co. from Detroit, Mich., and charging that a portion were adulterated and misbranded and that the remainder were misbranded.

Analyses of samples of the article showed that it consisted essentially of acetanilid (2.3 grains), aspirin (4.4 grains), and caffeine (¾ grain) per capsule.

The repackaged capsules were alleged to be adulterated in that their strength differed from that which they purported or were represented to possess, namely, (cartons) "Each Cap contains 3½ grs. acetanilid," since each capsule contained materially less than 3½ grains of acetanilid.

They were alleged to be misbranded: (1) In that they would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling, namely: (Carton) "One Capsule Usually Gives The Desired Results. If Necessary, Another May Be Taken In One Hour"; and (circular) "Take one Bromo-Cap with a swallow of water and repeat again in about an hour if not relieved, or until 3 doses have been taken. * * * A few Bromo-Caps, taken one every 2 Or 3 hours * * * 1 Bromo-Cap every 3 or 4 hours. * * * take 1 Bromo-Cap. Repeat in 1 or 2 hours. Then one every 3 or 4 hours. * * * Take one Bromo-Cap every 3 or 4 hours with large drinks of water. * * * Take one Bromo-Cap, another in 1 hour, then one every 3 or 4 hours. It may be advisable to take at least 12 altogether * * * a Bromo-Cap every 2 or 3 hours for a few doses. * * * Bromo-Cap taken with one or two large glasses of water. Thereafter take one Bromo-Cap every three or four hours until well." (2) In that the name "Bromo-Cap" on the carton was false and misleading since they contained no bromine or compound of bromine. (3) In that the statements, (carton) "Bromo-Caps Contain No Narcotic Drugs" and (accompanying circular) "A Quick, Sure Scientific Remedy That Takes the Place of Aspirin, Habit-Forming Headache Powders and Liquids," were false and misleading since they created the impression that the article contained neither dangerous drugs nor aspirin. (4) In that statements in the labeling representing that they would give relief and constitute an adequate treatment for rheumatic pains, colds, toothache, overindulgence in food or drink, mental fatigue, menstrual pains, feverish conditions, and sea or car sickness, were false and misleading since they would not be efficacious for such purposes. (5) In that the labeling failed to bear the common or usual names of the active ingredients other than acetanilid and did not state the quantity or proportion of acetanilid present, since the statement on the label was incorrect.

Both the repackaged and bulk capsules were alleged to be misbranded: (1) In that their labeling failed to bear adequate directions for use (in the case of the repackaged capsules) since the directions given provided for the administration of excessive quantities of acetanilid; and (in the case of the bulk capsules) since the labeling failed to bear warnings to the effect that because of their acetanilid content, frequent or continued use might be dangerous, causing serious blood disturbances, anemia, collapse, or dependence on the drug, and that they should not be given to children. (2) In that the labeling did not bear adequate warnings against use in those pathological conditions or by children where their use might be dangerous to health or against unsafe dosage or methods or duration of administration, in such manner and form, as are necessary for the protection of users, since it failed to bear warnings to the effect that because of their acetanilid content frequent or continued use might be dangerous, causing serious blood disturbances, anemia, collapse, or dependence on the drug, and that they should not be given to children.

The bulk capsules were alleged to be misbranded further in that the label did not bear the common or usual names of the active ingredients, since aspirin had been declared by its chemical name, "Acetylsalicylic Acid," rather than by its common or usual name.

On August 18, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

602. Misbranding of cold capsules and tablets. U. S. v. 4,300 Cold Special No. 2 Capsules and 74 Packages of Swiss Capsules (and 2 other seizures of cold remedies). Default decrees of condemnation and destruction. (F. D. C. Nos. 3866, 4695, 4909, 4913. Sample Nos. 50188–E, 50189–E, 50249–E, 50250–E, 50668–E, 60421–E.)

These preparations, when used according to directions, would supply acetanilid in amounts that would be dangerous to health. Their labeling also failed to bear adequate directions and warning statements, and they were misbranded further because the name of a portion, "Cold Special," and the statement on the label of the remainder, "For Simple Colds * * * For * * * Colds," were false and misleading since they did not constitute a treatment or preventive for colds. A portion also failed to bear the required ingredient and quantity of contents statements, was deceptively packaged, and failed to bear the name and place of business of the manufacturer, packer, or distributor.

Between February 25 and June 23, 1941, the United States attorneys for the Southern District of West Virginia, Eastern District of Virginia, District of Maryland, and the District of Oregon filed libels against the following quantities of cold remedies—4,870 capsules (3,500 in original bulk container labeled "Capsules Cold Special" and 114 cartons, each containing 12 repackaged capsules, labeled in part "Upjohn Cold Special") at Richmond, Va.; 5 bottles of Cold Special No. 2 and 74 packages of Cold Special Capsules at Charleston, W. Va.; 4,300 Cold Special No. 2 and 74 packages of Swiss Capsules at Baltimore, Md.; and 1 bottle of Cold Special No. 2 Tablets at Portland, Oreg., alleging that the articles had been shipped in interstate commerce within the period from on or about September 25, 1940, to on or about February 14, 1941, by the Upjohn Co., in part from Kalamazoo, Mich., and in part from New York, N. Y.; and charging that they were misbranded.

Analyses of samples of the cold preparations showed that they contained acetanilid, a quinine salt, camphor, podophyllin, and aloin.

The articles were alleged to be misbranded in that they would be dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the labeling. They were alleged to be misbranded further: (1) In that the labeling failed to bear adequate directions for use since (in the case of those at Charleston, Baltimore, and Portland) if used in accordance with the directions given they would have been dangerous to health; and (in the case of those at Richmond) since the directions given were inappropriate for articles of their composition. (2) In that the labeling failed to bear adequate warnings against use in those pathological conditions and by children where their use might be dangerous to health or against unsafe dosage and duration of administration, in such manner and form, as are necessary for the protection of users; and (in the case of those at Baltimore and Portland) in that the labeling failed to bear warnings against use in cases of nausea, vomiting, abdominal pain, or other symptoms of appendicitis, against its use by children, against frequent or continued use which might endanger the health of users by causing serious blood disturbances, anemia, collapse, or a dependence upon the drug, and against taking such amounts, or the continuation of its use for a period of time, which might prove injurious to the user. (3) In that the designation "Cold Special," appearing on the label of a portion, and the statements on the label of the remainder, "For Simple Colds * * * For * * * Colds," were false and misleading since they did not constitute a treatment for or preventive of the disease commonly known as "cold."

The repackaged lot at Richmond, Va., labeled "Upjohn Cold Special Capsules," was alleged to be misbranded still further (1) in that the label failed to bear the common or usual name of each active ingredient; (2) in that the label failed to bear the name and address of the manufacturer, packer, or distributor since the name "Grant Drug Co., Inc.," appearing on the label, was not qualified to show the connection that firm had with the article, and the firm's location was not stated; (3) in that the label failed to state the quantity of contents of the package; and (4) in that its container was so made, formed, and filled as to be misleading.

Within the period from June 12 to October 18, 1941, no claimant having appeared, judgments of condemnation were entered and the products were ordered destroyed.

603. Misbranding of physiological solution of sodium chloride and of dextrose in physiological solution of sodium chloride. U. S. v. 20 Bottles of Physiological Solution of Sodium Chloride; 18 Bottles, 447 Bottles, and 317 Bottles of Dextrose in Physiological Solution of Sodium Chloride. Default decrees of condemnation and destruction. (F. D. C. Nos. 4917 to 4919, incl., 4935. Sample Nos. 29086-E, 29087-E, 43447-E, 43449-E, 47597-E, 49066-E, 49067-E, 49069-E.)

These products would have been dangerous to health when used according to directions, because they had been contaminated with lead.

On or about June 14, 16, and 18, 1941, the United States attorneys for the Northern District of Illinois, Northern District of Ohio, and the Western District of Missouri filed libels against 20 bottles of physiological solution of sodium chloride at Chicago, Ill., and the following quantities of dextrose in physiological solution of sodium chloride—18 bottles of 10 percent strength at Cleveland, Ohio, and 276 bottles of 5 percent strength and 171 bottles of 10 percent strength at Kansas City, Mo., alleging that the articles had been shipped in interstate commerce on or about May 5, 13, 14, and 19, 1941, by the Upjohn Co., in part from Kalamazoo, Mich., and in part from New York, N. Y.; and charging

that they were misbranded. On June 16, 1941, a libel was filed in the Northern District of Texas against 289 bottles of 10 percent and 28 bottles of 25 percent dextrose in physiological solution of sodium chloride at Dallas, Tex., which had been consigned by the Upjohn Co., alleging that it had been shipped within the period from on or about March 7 to on or about May 23, 1941, from Kalamazoo, Mich.; and charging that it was misbranded.

The articles were alleged to be misbranded in that they would be dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the labeling, namely, "For Parenteral Injection."

On June 17, 1941, the shipper having consented to the destruction of the dextrose seized at Dallas, judgment of condemnation was entered and the product was ordered destroyed. Between July 10 and November 14, 1941, no claimant having appeared for the remaining products, judgments of condemnation were entered and the products were ordered destroyed.

604. Adulteration and misbranding of Zerbst's Capsules. U. S. v. 12 Dozen Cartons, 387 Dozen Cartons, 47 Dozen Cartons, 141 Dozen Cartons and 1,000 Sample Envelopes of Zerbst's Capsules. Consent decree of condemnation and destruction. (F. D. C. Nos. 4834, 4835. Sample Nos. 43426-E, 43427-E).

These capsules were found to consist essentially of acetanilid (4 samples examined contained 1.132, 1.282, 1.125, and 1.289 grains, respectively), together with caffeine, asafoetida, camphor, capsicum, and plant materials including aloin. They would be dangerous to health when used in the dosage or with the frequency or duration prescribed in the labeling, which failed to reveal the consequences which might result from their use. The labeling was further objectionable, as indicated below.

On June 11, 1941, the United States attorney for the Western District of Oklahoma filed a libel against 528 dozen small cartons, 59 dozen large cartons and 1,000 sample envelopes of Zerbst's Capsules at Oklahoma City, Okla., alleging that the article had been shipped in interstate commerce within the period from on or about January 28 to on or about February 18, 1941, by Zerbst Pharmacal Co. from St. Joseph, Mo.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that its strength differed from that which it purported or was represented to possess, namely, (label) "Each Capsule contains as active ingredients, Acetanilid 1 Grain," whereas each capsule contained materially more than 1 grain of acetanilid in each capsule.

It was alleged to be misbranded (1) in that the directions for use, namely, "Adults—To allay the discomfort in breaking up a common head cold, simple headache or neuralgia, take one capsule every half hour until three are taken, then one capsule in two or three hours until three more are taken. Children—12 years old, one capsule, repeated in three hours," were not appropriate for an article of the composition disclosed by the analysis, and were therefore inadequate; (2) in that the label failed to bear adequate warnings against its use by children or in those pathological conditions where its use might be dangerous to health, and against unsafe dosage or duration of administration, in such manner and form as are necessary for the protection of users; and (3) in that it was dangerous to health when used according to the directions appearing on the label as set forth above.

On October 1, 1941, the claimants having withdrawn their answers and having admitted the allegations of the libel and consented to the entry of a decree, judgment of condemnation was entered and the product was ordered destroyed.

605. Misbranding of Mrs. Moffat's Shoo Fly Powders for Drunkenness. U. S. v. 11¼ Dozen Packages of Mrs. Moffat's Shoo Fly Powders. Case tried to the court. Judgment for the Government. Decree of condemnation and destruction. (F. D. C. No. 3444. Sample No. 19574-E.)

This product contained tartar emetic and would be dangerous to health when used according to directions; and it would not be an effective and appropriate treatment for drunkenness as suggested in the labeling.

On November 27, 1940, the United States attorney for the Western District of New York filed a libel against the above-named product at Buffalo, N. Y., alleging that it had been shipped on or about November 2, 1940, by M. F. Groves' Son & Co. from Philadelphia, Pa.; and charging that it was misbranded.

Analysis of a sample of the article showed that it consisted of antimony and potassium tartrate (tartar emetic).

The article was alleged to be misbranded (1) in that it would be dangerous to health when used in the dosage or with the frequency or duration prescribed,

recommended, or suggested in the labeling, namely, "Directions—one of the powders may be given in beer, coffee, tea, or any other liquid"; and (2) that the statement "For Drunkenness" was false and misleading.

On April 28, 1941, M. F. Groves' Son & Co., claimant, having filed an answer denying the material allegations of the libel, the case came on for trial before the court. Evidence was introduced on behalf of the Government and the claimant, and on June 17, 1941, the court handed down the following opinion:

KNIGHT, *District Judge*. "The libelant seeks condemnation of certain articles of alleged drug products described as '11-¼ Dozen Packages of an article labeled in part: "Mrs. Moffat's Shoo Fly Powders for Drunkenness."' Libel is brought under the provisions of the Federal Food, Drug and Cosmetic Act of June 25, 1938, Title 21 U. S. C., and is based upon the claim that the aforesaid articles are misbranded under subdivision (a) and (j) of Section 352 of Title 21 U. S. C.

"It is admitted that the articles in question were shipped in interstate commerce, that is, from the State of Pennsylvania to the Ellicott Drug Co., at Buffalo, N. Y., on November 2, 1940, by the intervenor, M. F. Groves' Son & Co., who concededly is the owner and manufacturer of the articles in question, and that a representative of the libelant during said month purchased a quantity of the articles in question from the last-named company. The articles contained on the average 3.2 grains of potassium antimony tartrate (tartar emetic) and no other constituents.

"Section 321 (g) Title 21 U. S. C. provides, among other things, that a drug means '(2) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals'; and '(3) articles (other than food) intended to affect the structure or any function of the body of man * * *'; and (k) (same section) defines a label as 'a display of written, printed or graphic matters upon the immediate container of any article.' The label on the article in question clearly purports the content to be for use in the 'diagnosis, cure, mitigation, treatment or prevention' of drunkenness.

"The label in question is as follows: (Trade Mark) 'Mrs. Moffat's Shoo Fly Powders for Drunkenness 6 Powders—18 GM. Each Antimony & Potassium Tartrate In use 60 Years Use according to directions M. F. Groves' Son & Co. Since 1832 803 South Front Street Philad'a, Pa. Sold to Druggists only Price, 50 Cents a Box 19574 E Nov 14 1940 Directions.—One of the Powders may be given in Beer, Coffee, Tea or any other liquid. *Never give more than one Powder a day.* These powders are intended to be used by adults only, and should be kept from children.'

"Section 352, Title 21, supra, provides: 'A drug or device shall be deemed to be misbranded—(a) If its labeling is false or misleading in any particular' and '(j) If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.' Such misbranded article is liable to condemnation 'when introduced into or while in interstate commerce * * * or at any time thereafter, * * *.' Section 334, Title 21, supra.

"The questions at issue are (1) whether the labeling of the article aforesaid is false and misleading, and (2) whether the drug is dangerous to health when used in the dosage prescribed on the label. The libel must be sustained on the determination of either question in the affirmative.

"On behalf of the Government five physicians testified with respect to the effect of the use of antimony and potassium tartrate (tartar emetic) 'for drunkenness,' and with respect to the danger to health in its use in the dosage prescribed. On behalf of the claimant an officer of the intervenor gave testimony as to the amount of the article in question sold over a period of years.

"The proceeding is in rem. The burden rests upon the Government to establish its case only by a fair preponderance of the evidence. *U. S.* v. *Five 1-Pint Bottles*, etc., 9 F. Supp. 990; *U. S.* v. *23½ Dozen Bottles*, etc., 44 F. (2d) 831.

"A contention made by the intervenor is that it is necessary for the Government to show intent to deceive and defraud. While this was held to be the law under the Act of June 30, 1906, sec. 8 as amended by the Act of August 23, 1932, such is not the law under the Act of June 25, 1938, supra. The former statutes provided that an article should 'be deemed to be misbranded in case of drugs; * * * If its package or label shall bear * * * any statement * * * regarding the curative * * * effect * * *, which is false and fraudulent.' *Chichester Chemical Co.* v. *United States*, 49 F. (2d) 516, held that the

Government must prove actual intent to deceive. Under the present statute a drug is deemed to be misbranded 'if its labeling is false or misleading in any particular.' Intent is not necessary to be proved. Further, the aforesaid act of 1906, sec. 8, required that the misbranding must be 'false and misleading.' These are the words of the present statute. Under the act of 1906 numerous cases held that it was not necessary to show intent. In this circuit we find *U. S.* v. *Scaduto*, S. D. N. Y. decided January 16, 1920; *Von Bremem et al.* v. *United States*, 192 F. 904.

"It is urged that merely stating that the article is 'for drunkenness' is not sufficient to constitute offense of misbranding. The use of the words 'for drunkenness' is the equivalent of saying that it is a 'cure, mitigation, treatment or prevention' of drunkenness. The necessary implication is that it is for relief from drunkenness to at least some extent. In *U. S.* v. *Natura Co.*, 250 F. 925, cited by the intervenor, the indictment charged misbranding where the label stated that the drug was 'a natural remedy for certain specified diseases, and that it had proved effective in the treatment of such diseases.' There it was claimed that the word 'remedy' was synonymous with 'cure.' This was a criminal case, and it was held that the plaintiff had not established beyond a reasonable doubt that the statements on the label were both 'false and fraudulent.' This has no controlling bearing here.

"The physicians testifying on behalf of the Government were, one a pharmacologist, one an internist, one a neuropsychiatrist, one a specialist in therapeutics. Each testified that antimony and potassium tartrate (tartar emetic) is not a curative for drunkenness, that it is a drug not properly usable in the treatment of drunkenness, and that its use in the dosage shown on the label herein is dangerous to health. Each of these physicians had had extensive practice in his specialty. Each testified that the medical profession had long recognized that tartar emetic was a drug dangerous to be administered through the mouth; that its use through the mouth has been abandoned in the teaching field; and that the standard textbooks treat it as a poison. The testimony of these physicians is to the effect that tartar emetic taken through the mouth irritates the lining of the stomach and intestines, produces various injurious effects on various other organs of the body; that it is cumulative in its effect; that when taken in increased doses it causes nausea, vomiting, diarrhea and retching; and after absorption affects the liver and kidneys and increases the heart rate; that through the loss of the control of the muscles of the stomach the vomitus may be swallowed causing pneumonia. They say the medical profession for many years has not prescribed it to be taken through the mouth, except as it is so used in so-called brown mixture, which contains $\frac{1}{70}$ of a grain of this drug, and that its present use is almost entirely intravenous or intramuscular as a treatment for numerous tropical diseases. Brown mixture is used as a carrier with other drugs to make a cough syrup. They have given many other details pointing out the other effects from the use of this drug in the dosage prescribed.

"The pharmacopeia (ed. 1936) states the average dosage when taken internally as $\frac{1}{20}$ of a grain. The National Standard Dispensary (ed. 1907) gives it as $\frac{1}{2}$ to 1 grain taken every 15 minutes until several doses are taken or till emesis occurs. I find on reference to the edition of 1938 no reference is made to any repetition of the dose and that the dosage 'usually is about $\frac{1}{2}$ grain (.03 gm.).' The National Standard Dispensary (ed. 1907) also states that tartar emetic at one time was largely employed as an 'expectorant, diaphoretic, emetic, sedative, antiphlogistic, and counter-irritant, but at present its use has become greatly limited.' It states it is an irritant and that continued application causes 'a pustular eruption followed by deep sloughing'; that 'antimony depresses the sensory side of the spinal cord; * * * lowers * * * the pulse-force'; and blood pressure; that it is an irritant to the stomach and intestines and in toxic dose produces violent gastro-enteritis; that the purging following overdose of the drug 'is an effort made by the intestines to eliminate the poison, and is due also to the intense intestinal inflammation'; that it is very slowly absorbed and slowly eliminated; that as an emetic this drug causes great prostration and muscular relaxation, it is badly borne by children, by the aged, and by those who are enfeebled by disease; and never should be used when 'gastro-intestinal irritation or inflammation is present'; and that chronic poison sometimes results from the frequent administration of this drug.

"The edition of 1937 of the National Standard Dispensary further states this: 'Its emetic action is very certain, powerful, prolonged, but accompanied by much depression. * * * although because of the promptness of its emetic action recovery may occur after very large amounts one case is on record in which 2

grains proved fatal.' This work gives the dosage when used intravenously or intramuscularly at ½ to 2 grains given every alternate day and as a dosage internally 'as a diaphoretic or expectorant it may be given in quantities of from 1/40 to ⅛ grain. If used as an emetic the dose usually is about ½ grain.'

"The conclusion here is inescapable both that the label in question is false and misleading and that the drug is dangerous to health when used in the dosage prescribed on the label. While it may seem that the use of this emetic in some amount may be beneficial in cases of drunkenness because of the fact that it clears the stomach, the fact is that alcohol is absorbed into the blood stream within 20 minutes to half an hour after being taken into the stomach and, therefore, the emetic could not usually affect the action of the alcohol.

"The only evidence offered by the intervenor was that given by an official of the claimant to the effect that the powders in question have been sold for upwards of 60 years; that over 50,000 of the powder packages have been sold yearly for the last 10 years and that not a single case of harm or injury has ever been reported by an one to the manufacturers. Objection was raised to the reception of all this testimony. It was received subject to be stricken, if the court later so decided. It is believed that the testimony as to the number of packages of the powder that had been sold and the period of years over which it had been sold is competent and the ruling as made stands. However, the testimony that no complaints had been received is incompetent. *Goldstein* v. *United States*, 63 F. (2d) 609. It is clearly hearsay.

"The intervenor urges that the testimony on behalf of the intervenor is not outweighed by the testimony given by the experts called by the Government. We are to bear in mind in this connection that the only testimony now in the record offered by the intervenor is with reference to the number of packages sold and the period of time over which they were sold. While the intervenor cites numerous cases in which consideration had been given to the weight of expert testimony, none of these hold that it is to be given no weight. The weight of such testimony is for the court to determine. These cases present somewhat comparable situations where physicians have testified as experts: *U. S.* v. *Lee*, 107 F. (2d) 522, cert. denied 309 U. S. 654; *U. S.* v. *Dr. David Roberts Vet. Co.*, 104 F. (2d) 785; *U. S.* v. *American Laboratories*, 222 F. 104; *U. S.* v. *W. B. Wood Mfg. Co.*, D. C. E. D. Mo., decided May 12 1921; *Eleven Gross Packages etc.* v. *United States*, 233 F. 71; *Chichester Chemical Co.* v. *United States*, supra; *Hall* v. *United States*, 267 F. 795. The testimony of these physicians is largely based on their studies as physicians but not upon the actual use of the article in question. Certain of these physicians have testified to personal observation of the use of the drug in question. Testimony of these men is not to be entirely disregarded because they testified as experts. As against the testimony that a large number of packages of this drug have been sold during many years, we have the testimony of all of the five physicians that the drug itself is not a cure for drunkenness and that its use in the dosage prescribed is dangerous to health. Each of these physicians went into great detail in explaining the nature of the drug and its reactions upon the human system when taken internally.

"It is not necessary to decide whether the drug when taken in the dosage of any specific number of grains less than 3.2 may properly be taken in the treatment of drunkenness or whether such dosage would be dangerous to health. I do decide that the articles in question are misbranded, since the labels thereon are false and misleading, because antimony and potassium tartrate in the dosage of 3.2 grains (the average in the articles analyzed) is not a 'cure, mitigation, or treatment' for drunkenness as purported to be and also that it is misbranded, because the use of the drug in the dosage of 3.2 grains is dangerous to health.

"Libelant is entitled to an order adjudging and decreeing that the articles of drug product aforesaid be condemned according to the provisions of the statute."

On August 12, 1941, judgment of condemnation was entered and it was ordered that the product be destroyed, with the exception of 3 dozen boxes that were ordered turned over to the Food and Drug Administration for official use. Through inadvertence, the entire lot of seized goods was destroyed.

606. Misbranding of Alcoban. U. S. v. 7 Packages of Alcoban and 8 other seizures of Alcoban. Decrees of condemnation and destruction. (F. D. C. Nos. 3832, 4097, 4794, 4795, 5266, 5274, 5445, 5793 to 5797, incl., 5875. Sample Nos. 22375-E, 23106-E to 23109-E, incl., 44738-E, 44770-E, 44771-E, 55721-E, 60189-E, 60545-E, 61741-E, 65083-E, 73420-E.)

This product contained emetine hydrochloride and would be dangerous to health when used as directed or suggested in the labeling. Furthermore, its

labeling bore false and misleading claims regarding its efficacy in overcoming the liquor habit.

Between February 19 and September 23, 1941, the United States attorneys for the Districts of Oregon and Montana, and the Western District of Missouri, filed libels against 119 packages of Alcoban at Portland, Oreg., 12 packages at Missoula, Mont., and 9 packages at Kansas City, Mo., alleging that the article had been shipped in interstate commerce within the period from on or about July 10, 1940, to on or about August 25, 1941, by the Maffett Sales Corporation from Seattle, Wash.; and charging that it was misbranded. On May 23, August 2, and September 23, 1941, the United States attorneys for the District of Colorado and the Northern District of California filed libels against 123 boxes of Alcoban at Denver, Colo., and 229 packages of Alcoban at San Francisco, Calif., which had been consigned by the Maffett Sales Corporation, alleging that the article had been shipped in interstate commerce from Seattle, Wash., within the period from on or about November 19, 1940, to August 20, 1941; and charging that it was misbranded.

Analyses of samples of the article showed that it consisted of capsules containing emetine hydrochloride in amounts varying from 0.05 to 0.18 grain of ephedrine hydrochloride, pilocarpine hydrochloride, and milk sugar.

The article was alleged to be misbranded in that it would be dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the following labeling: "Dosage A. When Alcoban is dissolved in each Separate alcoholic drink—determination of correct dosage: 1. The contents of 1 capsule should be given every 15 to 20 minutes until 3 capsules are taken. If vomiting occurs, this should be regarded as the proper dose and the treatment may be so given at the rate of 6 capsules (6 drinks) every third day. 2. If no vomiting occurs on the 1 capsule per drink basis as above described, double the dosage to 2 capsules per drink. Wait one hour and administer only 2 such additional drinks. If vomiting occurs, then the correct dosage is 2 capsules per drink and this treatment may be given at the rate of 6 capsules (3 drinks) every third day. * * * B. When Alcoban is dissolved in bottles of alcoholic drink—determination of correct dosage: The bulk liquor should be prepared on the basis of 1 capsule per full size drink i. e., 2 capsules per pint of beer, 4 capsules per pint of wine or 6 capsules per pint of whiskey, gin, rum or other hard liquor. 1. Administer the drink at the equivalent of 1 capsule every 15 minutes until an amount of liquor containing 3 capsules of Alcoban has been consumed. If vomiting occurs, this should be regarded as the proper dose and the treatment may be so given at the rate of 6 capsules (6 drinks) every third day. 2. If no vomiting occurs on the 1 capsule per drink basis as above described, increase the dosage to 2 capsules per drink. Wait one hour and administer only 2 such additional drinks. If vomiting occurs, then the correct dosage is 2 capsules per drink and this treatment may be given at the rate of 6 capsules (3 drinks) every third day."

It was alleged to be misbranded further in that the statement on the carton "An aid in curbing the liquor habit" and statements in the circular which represented that it would be effective to curb the liquor habit were false and misleading since it would not be an appropriate or effective treatment for curbing the liquor habit.

Between April 17 and November 7, 1941, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

Nos. 607 and 608 report the seizure and disposition of drugs which would be dangerous to health when used in the manner recommended and suggested in the labeling, which recommended the introduction of the drug into the pregnant uterus.

607. Misbranding of Leunbach' Paste. U. S. v. 4 Packages of Leunbach' Paste, Complete Outfit; and 4 Packages of Leunbach' Paste Refill Tube (and 5 other seizure actions against Leunbach' Paste, Complete Outfit; and Leunbach' Paste Refill Tube). Default decree of condemnation and destruction with respect to one seizure. Remaining five seizure actions ordered removed and consolidated. Answers withdrawn and judgment of condemnation entered; product ordered delivered to Government. (F. D. C. Nos. 2668, 2674, 2676, 2826, 2827. Sample Nos. 5032–E, 5033–E, 20127–E, 28933–E, 28934–E, 32419–E, 32420–E, 33525–E.)

Between August 23 and December 30, 1940, the United States attorneys for the District of Columbia, the Southern District of Ohio, the Middle District of Pennsylvania, the Southern District of California, and the Northern District of Georgia filed libels against the following quantities of Leunbach' Paste

Complete Outfits and Leunbach' Paste Refill Tubes; 4 packages of the outfits and 4 packages of the refill tubes at Washington, D. C.; 4 packages of the outfits and 6 packages of the refill tubes at Cincinnati, Ohio; 1 package of the outfits and 7 packages of the refill tubes at Scranton, Pa.; 10 packages of the outfits and 16 packages of the refill tubes at Los Angeles, Calif.; and 10 packages of the refill tubes at Atlanta, Ga., alleging that the articles had been shipped in interstate commerce within the period from on or about March 7 to on or about August 16, 1940, by Merz & Co. Chemical Works. Inc., from Newark and East Orange, N. J.; and charging that they were misbranded.

Examination showed that the outfit contained a tube of paste and instruments for its application, and that the refill tubes contained the same paste. Analysis of the paste showed that it consisted essentially of soap, water, alcohol (approximately 2 percent) and potassium iodide (approximately 2 percent).

The articles were alleged to be misbranded in that they were dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the following labeling: (Circular found in complete outfit) "Technique of Injection Now carefully introduce rounded tip of cannula through external os. Gradually enter into canal by injecting smallest doses of paste ahead and following through with metal tip. In this way canal is naturally opened and small obstacles such as folds of mucosa pushed aside. No additional dilation is required. Guide 3½" metal tip through full length of canal until internal os has been passed. In the advanced stage of pregnancy take special care to introduce metal tip only until internal os has been passed—avoid puncturing of ovisac, also avoid detaching of placenta with metal tip. If difficulty of retention of paste is anticipated in advanced cases, a firm and high vaginal pack may be made. Some physicians have successfully used a technique to inject Leunbach' Paste into the upper fundus by attaching to the metal tip a piece of soft rubber tubing (catheter) long enough to reach behind the fetus. In cases of bad cervical laceration slide cervical plug over cannula tip far enough down to provide an effective 'stop-cock', thus preventing reflow of paste during injection. Then plug external os with gauze or tampon as soon as cannula is withdrawn. In cases of cervical stenosis attach a 2" to 3" piece of soft rubber tubing (catheter) to metal tip which may thus be guided through canal. In all cases, Leunbach' Paste is to be deposited at the lowest point of the fundus. To inject Paste roll up tube with turn-key Very Very Slowly And Carefully, and With Frequent Intermissions. Note on tube scale the quantity being injected. During injection withdraw cannula slightly to make such of avoiding infiltration and employing the lowest possible pressure. Injection should be timed by the watch and should require an average of one minute per gm. of Paste, that is ¼ hour should be taken to inject 15 gms. of Paste. * * * Occasionally a Leunbach' treatment fails to produce results. In such cases the physician should check that the paste was actually deposited in the lower fundus with injection, and that it was not reexpelled during or shortly after injection. Another reason for failure to respond may be unusual inertia. Where the Leunbach' treatment has been followed by but a few cramps with little or no bleeding and with the cervix remaining closed, a repeat of Paste injection is suggested within one week from date of first injection. If the date of the next estimated period is near, it is always advisable to wait, as many cases will still respond at this time. To prepare most thoroughly for a repeat Leunbach' treatment, inject Paste at night up to the point of overflow while injecting as slowly as possible and avoiding high pressure;" (leaflet found both in complete outfit and refill) "1. To prepare for treatment warm tube to body temperature and sterilize cannula. Before inserting cannula, make sure that at least 2 Gms. of homogeneous paste have exuded from its tip. Air must not enter with injection. Do not boil tube. To sterilize posterior vagina any recognized antiseptic, except zephiran or related chemicals, may be used. 2. Guide cannula carefully and slowly through cervical canal while injecting small doses of paste ahead. Introduce cannula until metal tip rests in lower fundus, protruding a trifle beyond internal os. Be careful not to puncture ovisac or detach placenta. 3. In every case paste is deposited at the lowest point of the fundus. To inject paste, roll up tube with turn-key very very slowly and carefully, with frequent intermissions, thereby decreasing pressure on membranes. During injection withdraw cannula slightly. Injection should be timed by the watch, to require an average of one minute per Gm. of Paste, e. g. ¼ hour should be taken to inject 15 Gms. of paste. 4. If strong tension, much bleeding or a re-expulsion of paste occur during injection, treat-

ment should be stopped. Should a temperature of 100° F. persist for at least 24 hours, or in case of hemorrhage, the outside complicating factor causing this condition must at once be determined and treated accordingly. A temporary rise in temperature during paste treatment is no sign of danger. 5. In those rare cases where the first paste treatment fails to produce results, it may be repeated a week later provided there is no bleeding. 6. For cases up to and including six weeks of gestation the use of the modified strength of Leunbach' Paste (identified as package 'M') is suggested in an average dose of 15 Gms. 7. Spontaneous and incomplete, as well as infected cases should be treated with a dose not exceeding 5 Gms. per month of gestation, up to a maximum of 25 Gms., injecting with but the slightest pressure. At term, Leunbach' Paste is contraindicated in the presence of placenta praevia and premature separation of placenta"; and (leaflet in both complete outfit and refill tube of lot seized at Los Angeles) "In those rare cases where the first paste treatment fails to produce results, it may be repeated a week later provided there is no bleeding. * * * For cases up to and including six weeks of gestation the use of the modified strength of Leunbach' Paste is suggested in an average dose of 15 Gms."

On October 7, 1940, no claimant having appeared for the lot seized at Atlanta, Ga., judgment of condemnation was entered and the product was ordered destroyed. On October 10, 1940, the decree was set aside, but on October 18, 1940, an order was entered reinstating the original judgment of condemnation and destruction.

Merz & Co. Chemical Works, Inc., appeared as claimant in the remaining seizures and filed answers denying the allegations of the libels. On March 24, 1941, the claimant filed a petition in the District Court for the District of Columbia praying removal of the case in that district and all other pending cases to the Eastern District of Pennsylvania for consolidation and trial. On March 25, 1941, an order was entered in the District Court for the District of Columbia in accordance with said prayer and the clerks of the various district courts were ordered to transmit to the Eastern District of Pennsylvania all records and papers in the proceedings pending in their respective jurisdictions.

On December 9, 1941, the answers filed by the claimant having been withdrawn by the receiver of the claimant corporation, which had filed a voluntary petition in bankruptcy, judgment of condemnation was entered and the products were ordered delivered to the Food and Drug Administration for its official use.

608. Misbranding of Leunbach' Paste. U. S. v. 1 Leunbach' Paste, Complete Outfit; and 7 Packages of Leunbach' Paste Refill Tube. Default decree of condemnation and destruction. (F. D. C. No. 7340. Sample No. 91220–E.)

On April 30, 1942, the United States attorney for the Northern District of Illinois filed a libel against the above-named drugs at Chicago, Ill., alleging that the articles had been shipped in interstate commerce on or about January 25, 1942, by the Doctors Pharmacy from Milwaukee, Wis.; and charging that they were misbranded. The articles were labeled in part: "Leunbach' Paste Complete Outfit"; or "Leunbach' Paste Refill Tube * * * Made in U. S. A. By Merz & Company Chemical Works, Inc., Newark, New Jersey."

The articles were alleged to be misbranded in that they were dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling. (The labeling accompanying the articles consisted of the circular and leaflet quoted in full in D. D. N. J. No. 607.)

On June 10, 1942, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

609. Adulteration and misbranding of Virgitalis, Rua-Balm, and Theobarb. U. S. v. Van Pelt & Brown, Inc. Plea of nolo contendere to first and second counts. Plea of guilty to remaining four counts. Total fines, $300. (F. D. C. No. 4170. Sample Nos. 50070–E, 50095–E, 50129–E, 50130–E.)

The Virgitalis possessed a potency of approximately one-third of that declared. The Rua-Balm contained less alcohol than the amount declared and its labeling failed to bear such adequate warnings as are necessary for the protection of users. The Theobarb Tablets contained less phenobarbital than the amount declared.

On September 19, 1941, the United States attorney for the Eastern District of Virginia filed an information against Van Pelt & Brown, Inc., Richmond, Va., alleging shipment on or about September 12 and 21, 1940, and January 9, 1941,

from the State of Virginia into the District of Columbia of quantities of the above-named articles which were adulterated and misbranded.

The Virgitalis was alleged to be adulterated in that its strength differed from that which it purported and was represented to possess since each tablet purported and was represented to possess an activity equivalent to that possessed by 1½ grains of whole digitalis leaf; whereas each tablet possessed an activity equivalent to not more than ½ grain of whole digitalis leaf. It was alleged to be misbranded in that the statement "Each Tablet Assays * * * 1½ grains Standardized Whole Digitalis Leaf (Physiologically Standardized)," appearing on the bottle label, was false and misleading.

The Rua-Balm was alleged to be adulterated in that its strength differed from that which it purported and was represented to possess since it was represented to contain 25 percent of alcohol, whereas it contained not more than 14 percent by volume of alcohol. It was alleged to be misbranded (1) in that the statement "Alcohol 25%," appearing on the carton and bottle label, was false and misleading; (2) in that it was fabricated from two or more ingredients and its label did not bear the common or usual name of each active ingredient; and (3) in that its labeling did not bear adequate warnings against unsafe methods or duration of administration in such manner and form as are necessary for the protection of users, since it consisted chiefly of methyl salicylate and might cause excessive irritation of the skin, particularly if applied with rubbing, and should not be permitted to get into the eyes or mucous membranes, and its labeling did not bear the warning that it might cause excessive irritation of the skin, particularly if applied with rubbing, and that the user should avoid getting it into the eyes or mucous membranes.

The Theobarb was alleged to be adulterated in that its strength differed from that which it purported and was represented to possess since each tablet was represented to contain ¼ grain of phenobarbital, whereas each tablet contained not more than 0.056 grain of phenobarbital. It was alleged to be misbranded in that the statement "Each Tablet Contains Phenobarbital ¼ Gr.," appearing on the bottle label, was false and misleading.

On October 16, 1941, pleas of nolo contendere as to counts 1 and 2 of the information and guilty as to counts 3, 4, 5, and 6 were entered on behalf of the defendant and the court imposed fines totaling $300.

610. Misbranding of Atop Nerve Tonic. U. S. v. 8 Dozen Bottles of Atop. Default decree of condemnation and destruction. (F. D. C. No. 6217. Sample No. 74150-E.)

In addition to failure to bear adequate warning statements, the labeling of this product bore false and misleading therapeutic claims.

On November 15, 1941, the United States attorney for the Southern District of New York filed a libel against 8 dozen bottles of Atop Nerve Tonic at New York, N. Y., alleging that the article had been shipped on or about September 15 and October 20, 1941, by the W. J. Gilmore Drug Co. from Pittsburgh, Pa.; and charging that it was misbranded.

Analysis of a sample of the article showed that it consisted essentially of chloral hydrate (12 grains per fluid ounce) and sodium bromide (29 grains per fluid ounce).

The article was alleged to be misbranded: (1) In that the labeling contained (a) no warning that it should not be taken by persons suffering from kidney diseases; (b) no warning that not more than the recommended dose should be taken; and (c) no warning that frequent or continued use might lead to mental derangement, skin eruptions, or other harmful effects. (2) In that representations in the labeling that it was an appropriate treatment for nervous exhaustion and that it relieved such symptoms as irritability, sleeplessness, headache, dyspepsia, eye fatigue, etc.; that it would overcome fear; that it would be an efficacious treatment for the delicate mental and emotional disorders of children; that it would prevent functional disturbances of the gastro-intestinal tract, cardiac system, and pelvic organs; that it would restore the normal impulses to the gastro-intestinal tract and relieve auto-intoxication; that it would help correct disorders of the endocrine glands; that it was an appropriate treatment for the effects of alcoholic indulgence; that it was conducive to quick recovery from surgical shock; that it was invaluable in anginoid cases and exceedingly helpful in other cardiac cases; and that it was of value in convalescence by increasing the appetite and assisting in regaining vitality, were false and misleading since it would not be efficacious for such purposes.

On December 3, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

611. Misbranding of Bron-Chu-Line Emulsion. U. S. v. 21 Bottles of Bron-Chu-Line Emulsion. Default decree of condemnation and destruction. (F. D. C. No. 5928. Sample No. 42975–E.)

In addition to failure to bear adequate warning statements, the labeling of this product contained false and misleading claims regarding its efficacy in the conditions indicated hereinafter.

On September 30, 1941, the United States attorney for the Western District of Pennsylvania filed a libel against the above-named product at Pittsburgh, Pa., alleging that the article had been shipped in interstate commerce on or about July 17, 1941, by the Johnstone Drug Sales Corporation from Rochester, N. Y.; and charging that it was misbranded.

Analysis showed that the article consisted essentially of creosote, calcium, sodium and phosphorus compounds, benzyl alcohol, methyl salicylate, and gum acacia emulsified in a mineral oil.

It was alleged to be misbranded in that the statements in the labeling, "Bron-Chu-Line * * * Antispasmodic * * * of rare value in the treatment of irritated conditions of the respiratory passages * * * Beechwood Creosote possess values as an anti-pathogen, equal to if not superior to carbolic acid, and has long been considered of superior worth where any tubercular tendency is involved. * * * Methyl Salicylate acts as an eliminant of urea, uric acid and other acid waste matter whose excess presence is detrimental to recovery, such an excess of waste acid matter being a common presence where coughs, colds and catarrhal conditions are persistent; * * * Calcium and Sodium Hypophosphites are reconstructive tonics. In respiratory affections there is a constant waste of these vital body salts through expectoration. Such waste lowers body resistance and the presence of these Hypophosphites in the prescription is to afford resupply for body need. * * * We especially recommend Bron-Chu-Line Emulsion in such cases that the usual lozenge or home remedy has failed to relieve," were false and misleading since they indicated that it was of value in conditions involving the bronchi or lungs; whereas it was of no such value since it was essentially an expectorant and was not an antispasmodic, and it was not of real value in the treatment of irritated conditions of the respiratory passages; Beechwood Creosote was not present in sufficient quantity to be an anti-pathogen, and methyl salicylate was not present in the article in sufficient quantity to be an eliminant of urea, uric acid, and other acid waste matter when used as directed, and urea, uric acid, and other waste matter are not commonly present in excess where coughs, colds, and catarrhal conditions are persistent; calcium and sodium hypophosphites are not reconstructive tonics; there is not a constant waste through expectoration of calcium and sodium hypophosphites in respiratory affections; calcium and sodium hypophosphites are not vital body salts; and waste of calcium and sodium hypophosphites does not lower body resistance; and the product would not be efficacious in cases in which the usual lozenge or home remedy had failed to provide relief. It was alleged to be misbranded further in that its labeling failed to bear adequate warnings against use in those pathological conditions such as persistent cough or high fever where its use might be dangerous to health, or against unsafe duration of administration, since the duration of administration was not limited to 10 days, nor was the warning in such manner and form as is necessary for the protection of users.

On November 25, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

612. Misbranding of Ches-O-Kol. U. S. v. 199 Pounds of a Drug and 16 Dozen Packages of the same drug labeled "Ches-O-Kol." Default decree of condemnation and destruction. (F. D. C. No. 4896. Sample No. 37049–E.)

The drum in which this product was shipped failed to bear adequate directions for use and a statement of the common or usual name of the active ingredients. A portion had been repackaged in jars and cartons which bore on the labels false and misleading curative and therapeutic claims.

On June 24, 1941, the United States attorney for the Western District of South Carolina filed a libel against a drum containing 199 pounds and 16 dozen packages of Ches-O-Kol at Spartanburg, S. C., alleging that the article originally had been shipped on or about January 21, 1941, by the William A. Webster Co. from Memphis, Tenn., and that a portion (16 dozen packages) had been repackaged in 1½-ounce bottles and was in possession of the Ches-O-Kol Co., Spartanburg, S. C.; and charging that both lots were misbranded.

Analysis showed that the article consisted essentially of camphor, menthol, eucalyptol, and turpentine in a petrolatum base.

The article in the original drum was alleged to be misbranded in that its labeling did not bear adequate directions for use, since there were no directions for use on the drum; and in that it had been fabricated from two or more ingredients and its label did not bear the common or usual name of each active ingredient. The repackaged product was alleged to be misbranded in that statements in the labeling which represented that it would be efficacious in the treatment of chest colds, head colds, sore throat, croup due to colds, pneumonia, rheumatism, all skin diseases, dry, tickling coughs, sinus trouble, hay fever, flu, and that it would penetrate and relieve congestion, were false and misleading since it would not be efficacious for such purposes.

On August 7, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

613. Misbranding of Comfortt Tablets. U. S. v. 196 Boxes each containing 12 Comfortt Tablets. Default decree of condemnation and destruction. (F. D. C. No. 4895. Sample No. 65614–E.)

These tablets, which contained acetophenetidin, aspirin, and caffeine, originally were shipped in bulk, but subsequently were repackaged by the consignee. After such repackaging, the labeling in addition to failure to bear adequate directions for use and the required warning statements, also failed to declare the aspirin present by its common or usual name.

On June 10, 1941, the United States attorney for the District of Colorado filed a libel against the above-named product, alleging that on or about March 30, 1940, a consignment of a drug product labeled in part "Special Compressed Tablets R/2020 Eng. Comfortt" had been shipped from St. Louis, Mo., to College Laboratories, Inc., Denver, Colo., and that thereafter the latter firm had repackaged said product in boxes labeled in part "Comfortt Tablets"; and charging that as so repackaged it was misbranded as follows:

(1) In that it failed to bear adequate directions for use since those appearing on the box, namely, "Take one tablet and repeat in 30 minutes if needed, then one every 2 hours if needed. See your physician promptly if not relieved," did not limit dosage; (2) in that the labeling did not bear adequate warnings against use in those pathological conditions where its use might be dangerous to health or against unsafe dosage or duration of administration in such manner and form as are necessary for the protection of users, since it failed to warn that frequent or continued use might be dangerous, causing serious blood disturbances, and that not more than the recommended dose should be taken; and (3) in that the label did not bear the common or usual names of the active ingredients, since aspirin had been declared by its chemical name of acetylsalicylic acid and not by its common or usual name.

On August 2, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

614. Misbranding of Dye's Compound Tablets and Dye's Laxative Pellets. U. S. v. 8 Dozen Packages of Dye's Compound Tablets and 2 Dozen Packages of Dye's Laxative Pellets. Default decrees of condemnation and destruction. (F. D. C. Nos. 5083, 5084, 5636. Sample Nos. 7678–E, 7679–E.)

The labeling of the laxative pellets failed to bear adequate directions for use and such adequate warnings as are necessary for the protection of users. The labeling of both products bore false and misleading curative and therapeutic claims, and the containers were substantially larger than was necessary.

On July 8 and September 11, 1941, the United States attorney for the Southern District of California filed libels against the above-named drugs at Los Angeles, Calif., alleging that they had been shipped in interstate commerce on or about May 8 and 21 and June 10, 1941 by Dr. J. H. Dye Medical Co. from Buffalo, N. Y.; and charging that they were misbranded.

Analyses of samples showed that the compound tablets consisted of plant extractives, including valeric acid and alkaloid-containing plant drugs; and that the laxative pellets consisted essentially of aloin, podophyllum resin, and hydrastis.

The laxative pellets were alleged to be misbranded (1) in that the labeling did not bear adequate directions for use since the directions called for the administration of a laxative over an indefinite period of time; (2) in that the labeling did not bear adequate warnings against use in those pathological conditions where its use might be dangerous to health or against unsafe duration of administration in such manner and form as are necessary for the protection of users, since the labeling did not warn that frequent and continued

use might result in dependence upon a laxative and that a laxative should not be taken when suffering from nausea, vomiting, abdominal pain, or other symptoms of appendicitis; and (3) in that the following statements on the label, "To assist in relieving headaches, coated tongue, bad breath, aggravated pimply skin, lassitude, indigestion and other distressing symptoms due to temporary constipation," and similar statements in Spanish, borne on the label, were false and misleading since the article would not be efficacious for the purposes recommended.

Dye's Compound Tablets were alleged to be misbranded in that statements on the label which represented that it would relieve the distressing symptom of functional dysmenorrhea, painful symptoms of certain female functional irregularities, and symptoms such as headache, nervousness, irritability, headache, backache, nausea, debility, rings under the eyes, melancholia, hysteria, loss of appetite, lack of sleep, and pains in various parts of the body; that it would build up physical resistance, improve digestion and assist one in obtaining more nourishment; that it would promote happy life and would increase vitality and personal magnetism, thus making every attractive woman full of animation; and that it was an appropriate preventive and treatment for amenorrhea, dysmenorrhea, menopause, menorrhagia, metritis, and ovaritis, were false and misleading since it contained no ingredients capable of producing such effects. Both products were alleged to be misbranded further in that the containers were so filled as to be misleading.

On August 14 and October 6, 1941, no claimant having appeared, judgments of condemnation were entered and the products were ordered destroyed.

615. Misbranding of Fernol Concentrate. U. S. v. 65 Bottles, 144 Bottles, and 237 Bottles of Fernol Concentrate. Default decrees of condemnation and destruction. (F. D. C. Nos. 4797, 6133, 6274. Sample Nos. 43436–E, 43904–E, 62944–E, 62997–E.)

In addition to failure to bear adequate directions for use and warning statements, the labeling of this product also contained false and misleading claims.

On or about June 2 and November 1 and 22, 1941, the United States attorneys for the District of Kansas and the Eastern District of Michigan filed libels against 65 bottles of Fernol Concentrate at Wichita, Kans., and 381 bottles of Fernol Concentrate at Detroit, Mich., alleging that the article had been shipped within the period from on or about February 21 to on or about November 15, 1941, by the Fernol Co. from Chicago, Ill., and from Kansas City, Mo.; and charging that it was misbranded.

Analyses of samples of the article showed that it consisted essentially of Epsom salt, extract of cascara sagrada, small proportions of magnesium carbonate, sodium phosphate, salt, iron and ammonium citrate, a sugar, saccharin, alcohol, and water.

The portion of the product located at Detroit was alleged to be misbranded: (1) In that the directions for use appearing on the label, "Average Directions for Taking Adults: Take two tablespoonsful before going to bed and one tablespoonful before or after each meal. As this preparation contains laxative as well as other ingredients, regulate the dose according to action on bowels. You should have two thorough bowel actions a day. Above dose is average, but decrease or increase as agreeable," were not adequate directions for use since the article was essentially a laxative drug and the said directions for use included no limitation on the duration of administration but suggested use for an indefinite period by reason of the following statement appearing in an accompanying leaflet, "Valuble Coupon Read Carefully When you have Three of these coupons, mail to Company as below and we will mail you promptly prepaid one bottle of Fernol Free. Just go to your druggist and buy two more bottles of Fernol and you will then have three coupons." (2) In that the statement appearing in an accompanying leaflet, "Send For 'The Fernol Method' Send penny post card or letter to Fernol Co., 800 N. Clark St., Chicago, Illinois for instructive information on the Fernol Method. It will be mailed you postage paid," referred to two other leaflets entitled "The Fernol Method of Weight Reduction" and "Proof," and by such reference incorporated in the labeling of the article the statement appearing in these two leaflets, and that these statements, which represented that the article was a safe or appropriate means of reducing weight, would improve the whole system, overcome arthritis, enable one to do hard work without feeling worn out, prevent one from becoming tired after working all day, make one feel fine, relieve stuffiness around

the heart, make one feel healthier or look younger, give more energy, act as a tonic, relieve chronic constipation, help in every way, prevent headaches, or remedy gall-bladder trouble, were false and misleading since the article would not be efficacious for such purposes.

The portion located at Kansas City was alleged to be misbranded: (1) In that the labeling failed to bear adequate warnings against use by children where its use might be dangerous to health or against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users, since the label bore no warning that frequent or continued use of the preparation might result in dependence on laxatives to move the bowels. (2) In that the warning on the label with reference to the avoidance of use of the article in the presence of symptoms of appendicitis was not prominently placed thereon with such conspicuousness as to render it likely to be read by the ordinary individual under customary conditions of purchase and use, since it appeared relatively inconspicuously on one panel of the label attached to the package as sold and did not appear in connection with the directions for use on the label headed "Paste This Label On Your Bottle After Making." (3) In that the name Fernol and the statements appearing in the labeling constituted a device that was false and misleading since it suggested and represented to purchasers that the article would be appropriate and effective in the treatment of obesity; whereas it would not be appropriate and effective in the treatment of said disease. (4) In that the statement on the label, "Magnesium carbonate, sodium phosphate, sodium chloride (salt), cascara, iron and ammonium citrate, saccharin, dextrose (grape sugar), caramel color (burnt sugar), magnesium sulfate (Epsom salt)," was misleading since it failed to reveal the material fact that the effect of the article was due essentially to its content of Epsom salt, that the other ingredients mentioned were present in relatively inconsequential amounts, and that some of them, namely, sodium chloride (salt), iron and ammonium citrate, saccharin, dextrose (grape sugar), caramel color (burnt sugar), were not active ingredients.

On September 15, 1941, and January 7, 1942, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

616. Misbranding of Hoyt's Compound. U. S. v. 29½ Dozen Packages and 32½ Packages of Hoyt's Compound. Default decree of condemnation and destruction. (F. D. C. No. 5182. Sample No. 52314-E.)

The labeling of this product failed to bear adequate directions for use and listed the ingredients in such a way as to create the impression that all were active; whereas all were not active. The labeling also bore false and misleading curative and therapeutic claims.

On August 2, 1941, the United States attorney for the Eastern District of Washington filed a libel against 29½ dozen 10-fluid ounce size packages and 32½ dozen 2-fluid ounce packages at Yakima, Wash., alleging that the article had been shipped in interstate commerce on or about May 27, 1941, by the Hoyt Chemical Co. from Denver, Colo.; and charging that it was misbranded.

Analyses of samples of the article showed that it consisted essentially of water, alcohol, sugar, and extracts of plant materials including a laxative plant drug.

The article was alleged to be misbranded in that its labeling failed to bear adequate directions for use since the directions provided for continuous administration; whereas it was a laxative and should not be administered continuously. It was alleged to be misbranded further in that names of ingredients other than active ingredients appeared on the label thereby creating the misleading impression that all the ingredients listed were active ingredients. It was alleged to be misbranded further in that statements in the labeling which represented that it was an appropriate treatment for diseases of the stomach, bowels and kidneys; would be efficacious in the treatment of run-down conditions and for skin and blood diseases; that it would relieve such symptoms as sour stomach, bloating, indigestion, belching, gas, nervousness, dizziness, spots before the eyes, tiredness, sluggishness, and muscular aches and pains, were false and misleading since it contained no ingredients capable of producing the effects claimed.

On September 24, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

617. Misbranding of Lacto-Kelpol, Evitades, and chaulmoogra oil. U. S. v. 33 Bottles of Lacto-Kelpol, 10 Bottles of Evitades, and 19 Packages of Chaulmoogra Oil. Default decree of condemnation and destruction. (F. D. C. Nos. 4333 to 4335, incl. Sample Nos. 55412–E, 55413–E, 55415–E.)

The labeling of the Lacto-Kelpol failed to bear adequate directions for use, and that of all three products contained false and misleading claims.

On April 23, 1941, the United States attorney for the Western District of Washington filed a libel against the above-named products at Seattle, Wash., which had been consigned by Seal-Ins Laboratories, Inc., alleging that they had been shipped on or about August 15 and October 4, 1940, and January 4, 1941, from Los Angeles, Calif.; and charging that they were misbranded.

Analyses of samples of the articles showed that the Lacto-Kelpol consisted essentially of an emulsion of mineral oil, agar agar, lactic acid (approximately 1 percent), and water; that the Evitades tablets contained extracts of plant drugs; and that the chaulmoogra oil was labeled properly as to its identity.

The Lacto-Kelpol was alleged to be misbranded (1) in that the bottle label and carton failed to bear adequate directions for use by children, since the directions were indefinite as to quantity; (2) in that its name, "Lacto-Kelpol Lactic Acid Emulsion," was false and misleading since it owed its therapeutic value to ingredients other than lactic acid, and kelp was not one of its ingredients; and (3) in that representations in an accompanying circular that it would be of value in the treatment of certain types of diarrhea, colitis, dysentery, and constipation, were false and misleading since it would not be effective for such purposes.

Evitades was alleged to be misbranded in that the following statements in an accompanying circular, "Evitades is mild in sedative action. Useful in treating insomnia; also, nervous disturbances of the menstrual period," were false and misleading since it would not be efficacious for the purposes recommended.

The chaulmoogra oil was alleged to be misbranded in that statements in an accompanying circular representing that it was a preventive and appropriate treatment for various types of arthritis were false and misleading since it would not be efficacious for such purposes.

On June 17, 1941, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

618. Misbranding of Real-Lax Chewing Laxative. U. S. v. 104 Dozen Packages of Real-Lax Chewing Laxative. Default decree of condemnation and destruction. (F. D. C. No. 5996. Sample No. 72101–E.)

This product was a peppermint-flavored gum containing phenolphthalein, and its labeling failed to bear such adequate warnings as are necessary for the protection of users.

On October 8, 1941, the United States attorney for the Southern District of California filed a libel against 104 dozen packages of the above-named product at Los Angeles, Calif., alleging that the article had been shipped in interstate commerce on or about July 10 and August 7, 1941, by the Pennsylvania Drug Products Corporation from Pittsburgh, Pa.; and charging that it was misbranded.

The article was alleged to be misbranded in that its labeling failed to bear adequate warnings against use in those pathological conditions where its use might be dangerous to health or against unsafe duration of administration in such manner and form as are necessary for the protection of users, since the labeling failed to bear a warning against use when abdominal pain, nausea, vomiting, or other symptoms of appendicitis are present and against frequent or continued use which might result in dependence upon laxatives.

On October 28, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

619. Misbranding of Vinco Herb Tablets. U. S. v. 208 Small Boxes and 22 Large Boxes of Vinco Herb Tablets. Default decree of condemnation and destruction. (F. D. C. No. 5202. Sample Nos. 42425–E, 42426–E.)

The labeling of this product failed to bear adequate directions for use and such adequate warnings as are necessary for the protection of users and also bore false and misleading curative and therapeutic claims. Both sizes of packages were substantially larger than was necessary to hold the contents. The labeling of the small packages failed to bear certain mandatory labeling statements in such manner that they might be read and understood under ordinary conditions of purchase and use.

On July 22, 1941, the United States attorney for the Western District of Pennsylvania filed a libel against the above-named product at Pittsburgh, Pa., alleging that the article had been shipped on or about October 28, 1940, by the Vinco Herb Co. from Dayton, Ohio; and charging that it was misbranded.

Analysis showed that the article consisted essentially of aloe and extracts of plant drugs including capsicum and an emodin-bearing drug. The tablets in the small packages occupied 26 percent of their capacity and the tablets in the large packages occupied 42½ percent of their capacity.

The article in both sized packages was alleged to be misbranded (1) in that the labeling failed to bear adequate directions for use since the directions provided for taking the tablets over a period of 10 days, whereas a laxative should be taken only occasionally; (2) in that the labeling failed to bear adequate warnings against use by young children where its use might be dangerous to health or against unsafe dosage or duration of administration as are necessary for the protection of users since the product was essentially a laxative and there was no warning that frequent or continued use might result in dependence on laxatives; (3) in that statements in the labeling representing that it was an appropriate treatment for coated tongue, flatulence, sour stomach, simple headache, acid indigestion, listlessness, lazy feeling, bad breath, sluggishness, dull eyes, and sallow skin and that it would make life happy and enjoyable and would provide a clean, healthy condition of the mind and body, were false and misleading since it was a laxative and the various disease conditions for which it was recommended may be due to causes other than constipation; and (4) in that its containers were so made, formed, or filled as to be misleading.

The product in the small packages was alleged to be misbranded further (1) in that the name and address of the manufacturer, the declaration of the quantity of the contents, and the statement of the ingredients required by or under authority of law to appear on the labeling were not placed on the label with such conspicuousness and in such terms as to make them likely to be read by the ordinary individual under customary conditions of purchase and use since all these statements appeared on the bottom of the box; and (2) in that certain statements appeared in several foreign languages upon the box and certain statements and other information required by or under authority of law did not appear on the box in these foreign languages.

On August 22, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

620. Misbranding of quinine sulfate. U. S. v. 1,056 Bottles of Quinine Sulfate. Default decree of condemnation and destruction. (F. D. C. No. 4398. Sample No. 70227-E.)

The labeling of this product failed to bear adequate directions for use, and its containers were filled only to approximately one-half of their capacity.

On April 19, 1941, the United States attorney for the Eastern District of Virginia filed a libel against 1,056 bottles of quinine sulfate at Richmond, Va., alleging that the article had been shipped in interstate commerce on or about March 29, 1941, by the Carroll Chemical Corporation from Baltimore, Md.; and charging that it was misbranded. It was labeled in part: "National Brand Quinine Sulphate * * * ¼ Oz."

The article was alleged to be misbranded in that the labeling did not bear adequate directions for use; and in that its container was so made, formed, or filled as to be misleading.

On October 17, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO COMPLY WITH OFFICIAL OR OWN STANDARDS

621. Adulteration and misbranding of Russian oil and citrate of magnesia. U. S. v. James J. Kaplan (Diamond Drug & Magnesia Co.). Plea of guilty. Fine, $30. (F. D. C. No. 2841. Sample Nos. 87090-D, 2247-E, 2261-E.)

The mineral oil was represented to be U. S. P. mineral oil, i. e., heavy mineral oil; whereas it was light mineral oil. The citrate of magnesia contained less magnesium citrate and less citric acid than the amounts specified by the United States Pharmacopoeia.

On October 28, 1940, the United States attorney for the District of Massachusetts filed an information against James J. Kaplan, trading as the Diamond

Drug & Magnesia Co., Boston, Mass., alleging shipment on or about January 20, February 20, and April 4, 1940, from the State of Massachusetts into the States of Rhode Island and New Hampshire of quantities of the above-named products which were adulterated and misbranded. The articles were labeled in part: "Genuine * * * Russian Oil Type U. S. P. Mineral Oil * * * General Drug & Oil Co., Inc."; and "Peerless Effervescing Solution of Citrate of Magnesia U. S. P. * * * Distributed by General Drug & Oil Co., Boston, Mass."

The Russian oil was alleged to be adulterated in that it purported to be or was represented as a drug which is recognized in the United States Pharmacopoeia, under the names "Liquid Petrolatum" and "White Mineral Oil", but its strength differed from and its quality fell below the standard set forth in such compendium, since the specific gravity of samples taken from the two shipments was 0.8471 and 0.8479, respectively, at 25° C., and the kinematic viscosity of said samples was 0.173 and 0.1745 at 37.8° C., whereas the pharmacopoeia specifies that the specific gravity of liquid petrolatum or white mineral oil shall be not less than 0.860 at 25° C., and that its kinematic viscosity shall be not less than 0.381 at 37.8° C., and the respect in which the strength or quality of the article differed from the standard set forth in said compendium was not plainly stated on the label. It was alleged to be misbranded (1) in that the statements "Genuine Russian Oil," "U. S. P. Mineral Oil," and "Pure Russian Oil," together with the design showing a facsimile of the former Russian emblem, borne on the bottle label, were false and misleading, since they represented that it consisted of Russian oil, namely, liquid petrolatum or white mineral oil; whereas it did not so consist, but did consist of light liquid petrolatum (or light white mineral oil); and (2) in that it was light liquid petrolatum or light white mineral oil and was offered for sale and sold under the name of another drug.

The citrate of magnesia was alleged to be adulterated in that it purported to be or was represented as a drug which is recognized in the United States Pharmacopoeia under the names "Liquor Magnesia Citratis" and "Solution of Citrate of Magnesia," but its strength differed from and its quality fell below the standard set forth in that compendium, since it contained in each 100 cubic centimeters an amount of magnesium citrate corresponding to not more than 1.53 grams of magnesium oxide and 10 cc. of the article contained citric acid equivalent to not more than 24.18 cc. of half-normal hydrochloric acid; whereas the pharmacopoeia specifies that solution of citrate of magnesium shall contain in each 100 cc. an amount of magnesium citrate corresponding to not less than 1.6 grams of magnesium oxide, and that 10 cc. of the solution shall contain citric acid equivalent to 26 cc. of half-normal hydrochloric acid, and the difference in strength and quality from such standard was not plainly stated on the label. It was alleged to be misbranded in that the statements "Solution of Citrate of Magnesia U. S. P." and "Liquor Magnesia Citratis," borne on the bottle label, were false and misleading, since they represented that it consisted of solution of magnesium citrate or liquor magnesii citratis as defined by the United States Pharmacopoeia, whereas it did not so consist.

On April 7, 1942, the defendant entered a plea of guilty and the court imposed a fine of $30.

622. Adulteration and misbranding of carbon dioxide and oxygen mixture and compressed oxygen gas. U. S. v. Wall Chemicals Corporation. Plea of guilty. Fine, $120. (F. D. C. No. 5519. Sample Nos. 27568–E, 27965–E, 39616–E.)

The strength of these products differed from and their purity and quality fell below that which they were labeled as possessing.

On December 4, 1941, the United States attorney for the Northern District of Illinois filed an information against the Wall Chemicals Corporation, Chicago, Ill., alleging shipment on or about April 10, September 7, and October 22, 1940, from the State of Illinois into the States of Indiana and Missouri of quantities of carbon dioxide and oxygen mixture and of a quantity of compressed oxygen gas.

The carbon dioxide and oxygen mixture was alleged to be adulterated in that its strength differed from and its quality fell below that which it was represented to possess in that the drug in one shipment was represented to contain 10 percent of carbon dioxide and that in the other shipment was represented to contain 5 percent of carbon dioxide; whereas the former contained not more than 7 percent and the latter not more than 2.6 percent of carbon dioxide.

The compressed oxygen gas was alleged to be adulterated in that its strength differed from and its purity and quality fell below that which it was represented to possess in that it was represented to contain 7 percent of carbon dioxide; whereas it contained not more than 3.4 percent of carbon dioxide.

The carbon dioxide and oxygen mixture was alleged to be misbranded in that the statements "10% Carbon Dioxide" and "5% Carbon Dioxide", borne on the respective labels, were false and misleading since the article contained less carbon dioxide than so represented.

The compressed oxygen gas was alleged to be misbranded in that the statement "CO_2—7%," borne on the cylinder, was false and misleading since it contained less than 7 percent, namely, not more than 3.4 percent of carbon dioxide. It was alleged to be misbranded further in that the statement "Oxygen Gas," borne on the tags attached to the cylinder, was false and misleading since it represented and suggested that the article consisted wholly of oxygen gas, whereas it did not consist wholly of oxygen gas but did consist of a mixture of oxygen and carbon dioxide gases. It was alleged to be misbranded further in that it was in package form, and its label failed to bear an accurate statement of the quantity of the contents in terms of weight or measure.

On December 31, 1941, a plea of guilty was entered on behalf of the defendant and the court imposed a fine of $120 and costs.

623. Adulteration and misbranding of Vaxamine. U. S. v. 73 Vials of Vaxamine. Default decree of condemnation and destruction. (F. D. C. No. 5637. Sample No. 23105-E.)

This article was contaminated with aerobic sporeforming and nonsporeforming micro-organisms and molds.

On September 8, 1941, the United States attorney for the Northern District of California filed a libel against 73 vials of Vaxamine at San Francisco, Calif., alleging that the article had been shipped in interstate commerce on or about June 6, 1941, by the Intra Products Co. from Denver, Colo.; and charging that it was adulterated and misbranded. It was labeled in part: "20 cc. Intramuscular Intravenous Intradermal Solution Vaxamine Single Strength For Non-Specific Therapy."

The article was alleged to be adulterated in that its purity or quality fell below that which it purported or was represented to possess, since it contained living micro-organisms and therefore was not of a sufficiently high standard of purity or quality to be suitable for intramuscular, intravenous, and intradermal administration. It was alleged to be misbranded in that the statement "Intramuscular Intravenous Intradermal Solution" was false and misleading as applied to an article contaminated with living micro-organisms.

On October 3, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

624. Adulteration and misbranding of Mackenzol. U. S. v. 25 Bottles of Mackenzol. Default decree of condemnation and destruction. (F. D. C. No. 4976. Sample No. 11177-E.)

This product was not an antiseptic and germicide as represented. Its labeling bore false and misleading curative and therapeutic claims, and the bottle label did not bear a declaration of the quantity of the contents.

On June 24, 1941, the United States attorney for the Western District of Texas filed a libel against 25 bottles of Mackenzol at San Antonio, Tex., which had been consigned by R. and F. Schweickhardt, alleging that the article had been shipped on or about January 16, 1941, from St. Louis, Mo.; and charging that it was adulterated and misbranded.

Analysis showed that the article was a viscous liquid containing chiefly mineral oil and small amounts of volatile oils, including eucalyptol, thymol, methyl salicylate, and guaiacol compound and benzoic acid compound. Bacteriological examination showed that it was not an antiseptic.

The article was alleged to be adulterated in that its strength differed from that which it purported to possess, namely, "Antiseptic and Germicidal Compound," since it was not an antiseptic.

It was alleged to be misbranded in that representations in the labeling that it was an antiseptic and germicide; that it was guaranteed under the Food and Drugs Act; that it was antagonistic to all pathogenic organisms, and was healing; that it was efficacious in the treatment of chronic laryngitis due to tuberculosis in chronic bronchitis, acute and chronic nasal catarrh, especially where there was great discharge; that it was of much value in the treatment of

ulcerations and inflammation of the nose and throat, and possessed true healing virtues after the application of an aqueous alkaline or boric acid wash or douche; and that it was the best antiseptic for consumption, catarrh, cough, sore throat, burns, scalds, piles, leucorrhea, uterine affections, eczema, and all disorders of the skin; were false and misleading since it was not an antiseptic and germicide and would not be efficacious for the purposes recommended.

On November 18, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

625. Adulteration of ether. U. S. v. 83 Cans of Ether for Anesthesia. Default decree of condemnation and destruction. (F. D. C. No. 5641. Sample No. 43555–E.)

Analysis of this product showed the presence of aldehydes and ketones in 2 of the 10 cans examined.

On September 8, 1941, the United States attorney for the Western District of Oklahoma filed a libel against 83 cans of ether at Oklahoma City, Okla., alleging that the article had been shipped in interstate commerce on or about March 13, 1940, by Mallinckrodt Chemical Works from St. Louis, Mo.; and charging that it was adulterated in that it purported to be or was represented as a drug, the name of which is recognized in the United States Pharmacopoeia and its quality and purity fell below the standard set forth in the pharmacopeia since it is specified under tests for purity therein that ether shall be free from aldehydes and ketones.

On October 11, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

626. Adulteration and misbranding of thyroid powder. U. S. v. 15 Pounds of Thyroid Powder. Consent decree of condemnation and destruction. (F. D. C. No. 5942. Sample No. 65865–E.)

This product fell below the minimum potency required by the United States Pharmacopoeia, since it contained not more than 0.134 percent of iodine in thyroid combination; whereas the pharmacopoeia provides that thyroid contain not less than 0.17 percent of iodine in thyroid combination.

On October 4, 1941, the United States attorney for the District of Columbia filed a libel against 15 pounds of thyroid powder at Denver, Colo., which had been consigned by the H. H. Johnston Laboratories, alleging that the article had been shipped in interstate commerce on or about August 18, 1941, from Hollywood, Calif.; and charging that it was adulterated and misbranded. It was labeled in part: "H. H. Johnston Laboratories * * * Thyroid Powder U. S. P. XI."

The article was alleged to be adulterated in that it purported to be or was represented as a drug the name of which is recognized in the United States Pharmacopoeia and its strength differed from the standard set forth in the pharmacopoeia. It was alleged to be misbranded in that the designation "Thyroid Powder U. S. P. XI," borne on the container, was false and misleading.

On October 17, 1941, the H. H. Johnston Laboratories having filed an acceptance of service and authorization for taking of final decree, judgment of condemnation was entered and the product was ordered destroyed.

VITAMIN PREPARATIONS

627. Adulteration and misbranding of Dean's Vitamin Concentrate Capsules. U. S. v. 8 Dozen Retail Cartons of Dean's Vitamin Concentrate Capsules. Default decree of condemnation and destruction. (F. D. C. No. 5962. Sample No. 42956–E.)

This product was labeled as containing 1,000 units of vitamin D per capsule and was also labeled to indicate that it contained a substantial amount of vitamin G (B_2); whereas it contained not more than 800 units of vitamin D and but an inconsequential amount of vitamin G (B_2), namely, approximately one-eightieth of the minimum daily requirement.

On October 7, 1941, the United States attorney for the Western District of Pennsylvania filed a libel against 8 dozen cartons, each containing 25 dozen capsules, of the above-named product at Pittsburgh, Pa., alleging that it had been shipped in interstate commerce on or about April 18, 1941, by the Purity Drug Co., Inc., from Passaic, N. J.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and was represented to

possess. It was alleged to be misbranded in that the following statements on the label, "Each Capsule Contains Not Less Than * * * Vitamin D 1,000 units * * * Vitamin Concentrate Capsules containing vitamins * * * G (B_2)," were false and misleading when applied to an article containing less than 1,000 units of vitamin D and an inconsequential amount of riboflavin (vitamin G or B_2).

The article was also alleged to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in F. N. J. No. 3642.

On November 25, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

628. Adulteration of vitamin B complex capsules. U. S. v. 25,000 Capsules of Vitamin B Complex Improved. Default decree of condemnation and destruction. (F. D. C. No. 6039. Sample No. 53411-E.)

Examination of this product showed that it contained not more than 200 U. S. P. (International) units of vitamin B_1 per capsule, whereas it was represented as containing 333 International Units of vitamin B_1 per capsule.

On October 20, 1941, the United States attorney for the Southern District of California filed a libel against 25,000 capsules of vitamin B complex at Los Angeles, Calif., alleging that the article had been shipped in interstate commerce on or about May 15, 1941, by Miller Laboratories from Cleveland, Ohio; and charging that it was adulterated in that its strength differed from and its quality fell below that which it was represented to possess. The article was invoiced as "Vitamin B complex Improved, B_1—333 Units Int."

On December 30, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

629. Adulteration and misbranding of Vitagen. U. S. v. 21 Cases of Vitagen. Default decree of condemnation. Product ordered distributed to various charitable institutions. (F. D. C. No. 5683. Sample No. 65595-E.

This product was approximately 70 percent deficient in vitamin A and approximately 50 percent deficient in vitamin C.

On September 12, 1941, the United States attorney for the District of Colorado filed a libel against 21 cases of Vitagen at Denver, Colo., which originally had been consigned by College Laboratories, Inc., from Denver, Colo., to Seattle, Wash., and had been returned alleging that the article had been shipped in interstate commerce on or about April 22, 1941, from Seattle, Wash.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that valuable constituents, namely, vitamins A and C, had been wholly or in part omitted or abstracted therefrom. It was alleged to be misbranded in that the statements, "two teaspoons of Vitagen contains approximately: 2810 international units of A, 450 units of C," were false and misleading when applied to an article of lower vitamin content.

On November 14, 1941, no claimant having appeared, judgment of condemnation was entered and it was ordered that the product be distributed to various charitable institutions.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS IN THE LABELING

630. Misbranding of Zalco-Septic. U. S. v. Sylvia Zalk (Zalco Co.). Plea of guilty. Fine, $20. (F. D. C. No. 4143. Sample Nos. 8286-E, 75133-D.)

This product did not possess the antiseptic properties claimed for it.

On July 28, 1941, the United States attorney for the District of Minnesota filed an information against Sylvia Zalk, trading as the Zalco Co. at St. Paul, Minn., alleging shipment on or about February 1 and September 25, 1940, from the State of Minnesota into the State of North Dakota, of quantities of Zalco-Septic that was misbranded. The article was labeled in part: "Zalco-Septic (Antiseptic Solution)."

Analysis showed that the article consisted essentially of water, alcohol, and small proportions of menthol, eucalyptol, thymol, methyl salicylate, and boric acid. Bacteriological examination showed that it was not antiseptic.

The article was alleged to be misbranded in that the statements, "Zalco-Septic (Antiseptic Solution) * * * Nasal Douche: Add one part of Zalco-Septic to 4 or 5 parts of warm water * * * Feminine Hygiene: Add 1 part of Zalco-Septic to 10 parts of warm water," borne on the bottle label, were false and misleading since they represented that when used in the dilutions recom-

mended, it was an antiseptic within the meaning of the law; whereas it was not an antiseptic within such meaning, and it did not purport to be and was not represented as an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.

On November 4, 1941, a plea of guilty was entered on behalf of the defendant and the court imposed a fine of $20.

631. Misbranding of dextrose in physiologic sodium chloride solution. U. S. v. 7 Cases of Dextrose. Default decree of condemnation and destruction. (F. D. C. No. 4818. Sample No. 49411–E.)

This product, which was intended for intravenous injection, was found to contain lead.

On May 24, 1941, the United States attorney for the Eastern District of Louisiana filed a libel against 7 cases of the above-named product at New Orleans, La., alleging that the article had been shipped in interstate commerce on or about March 6 and April 19, 1941, by Hospital Liquids, Inc., from Chicago, Ill.; and charging that it was misbranded in that the statement "Dextrose 5 percent in Physiologic Sodium Chloride Solution Sterile and Non-Pyrogenic" was false and misleading since the label failed to reveal that the article contained lead and was unsuitable for intravenous injection.

On July 8, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

632. Misbranding of Bleything Concentrated Vegetable Compounds. U. S. v. 34 Packages of Concentrated Vegetable Compound Bleything Formula No. 201–A and 22 Packages of Concentrated Vegetable Compound Bleything Formula No. 201–B. Decree of condemnation and destruction. (F. D. C. No. 5468. Sample Nos. 65836–E, 65837–E.)

On August 29, 1941, the United States attorney for the District of Colorado filed a libel against the above-named products at Denver, Colo., which had been consigned by Bleything Laboratories, alleging that the articles had been shipped on or about January 4 and May 4, 1941, from Los Angeles, Calif.; and charging that they were misbranded.

Examination of samples of the articles showed that Formula No. 201–A consisted of tablets weighing approximately 8 grains each, which contained dried plant material yielding less than 1 grain of total mineral constituents; and that Formula No. 201–B consisted of tablets weighing approximately 8 grains each, which contained dried plant material yielding less than 1½ grains of total mineral constituents.

The articles were alleged to be misbranded in that designations in the labeling which constituted devices implying that Formula No. 201–A would supply something which would combat excessive acidity and acidosis; and that Formula No. 201–B would supply minerals which ward off alkalinity and alkalosis, were false and misleading since the articles could not be relied upon by physicians and were not effective for such purposes.

They were also alleged to be misbranded under the provisions of the law applicable to foods, as reported in F. N. J. No. 3424.

On October 17, 1941, Bleything Laboratories having signed an acceptance of service and authorization for taking of final decree, judgment of condemnation was entered and the product was ordered destroyed.

633. Misbranding of Earles Vital Vim. U. S. v. 8 Cases of Wheat Germ. Default decree of condemnation and destruction. F. D. C. No. 4770. Sample No. 47271–E.)

On May 19, 1941, the United States attorney for the Northern District of Illinois filed a libel against 8 cases, each containing 24 18-ounce packages, of a product labeled "Earles Vital Vim * * * Pure Wheat Germ" at Chicago, Ill., alleging that the article had been shipped by W. H. Earles Co. on or about April 25, 1941; and charging that it was misbranded.

Analysis of a sample of the article showed that it was essentially wheat germ as labeled.

The article was alleged to be misbranded in that statements in the labeling which represented that it was efficacious to restore and maintain health and vigor; that it would be efficacious in the prevention and treatment of overweight, underweight, fatigue, colitis, constipation, neuritis, arthritis, stomach troubles, indigestion, high blood pressure, hardening of the arteries, and sleeplessness; that it would be efficacious to strengthen the digestive organs, assist intestinal activity, and bring about good digestion and proper assimilation; and that it

would be efficacious to soothe the nerves and improve the circulation, tone the arteries, invigorate the heart muscles and normalize blood pressure; and ward off or prevent common colds or grip, were false and misleading since it would not be efficacious for such purposes.

The article was alleged to be misbranded also under the provisions of the law applicable to foods, as reported in F. N. J. No. 2994.

On October 1, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

634. Misbranding of Effervescent Kruschen Salts. U. S. v. 21 Dozen Packages of Effervescent Kruschen. Default decree of condemnation and destruction. (F. D. C. No. 5214. Sample No. 42575-E.)

On July 25, 1941, the United States attorney for the Western District of Pennsylvania filed a libel against 21 dozen 5-ounce packages of Effervescent Kruschen Salts at Pittsburgh, Pa., alleging that the article had been shipped on or about April 23, 1941, by the Johnstone Drug Sales Corporation from Rochester, N. Y.; and charging that it was misbranded.

Analysis of a sample of the article showed that it consisted essentially of anhydrous Epsom salt, (18.7 percent), with small proportions of common salt (sodium chloride), potassium chloride, sodium sulfate, potassium sulfate, sodium bicarbonate, and citric acid.

It was alleged to be misbranded in that statements in an accompanying circular which created the impression that it constituted an effective agent for reducing weight, that it had a stimulating effect on the liver and bowels, and that it acted as a mild diuretic, were false and misleading since it would not be efficacious for such purposes.

On November 19, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

635. Misbranding of Joint-Ease. U. S. v. 29 Tubes and 11 Tubes of Joint-Ease (and 1 other seizure of Joint-Ease). Default decree of condemnation and destruction. (F. D. C. Nos. 6002, 6303. Sample Nos. 59034-E, 59035-E, 87120-E, 87121-E.)

On October 8 and November 28, 1941, the United States attorney for the District of Columbia filed libels against 125 1-ounce tubes and 56 2½-ounce tubes of Joint-Ease at Washington, D. C., alleging that the article had been shipped in interstate commerce within the period from on or about July 7 to on or about October 23, 1940, by Pope Laboratories from Hallowell, Maine; and charging that it was misbranded.

Analyses of samples of the article showed that it consisted essentially of salicylic acid and volatile oils including eucalyptol, camphor, menthol, methyl salicylate, and turpentine oil incorporated in petrolatum.

The article was alleged to be misbranded in that various statements in the labeling and the designs showing portions of the human anatomy, which represented that it would be efficacious in the treatment of joint diseases, would ease joints, relieve minor joint aches and pains, muscular lameness, strained muscles, stiff neck, and all surface muscular aches and pains, also aches and pains affecting the neck, shoulders, elbows, fingers, knees, and feet, and that it would provide a competent treatment for irritations or miseries due to common colds in nose, throat, and chest, were false and misleading, since it would not be efficacious for such purposes.

On October 29 and December 22, 1941, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

636. Misbranding of papaya syrup. U. S. v. 243 Dozen Bottles and 46 Dozen Bottles of Tropical's Original Papaya Syrup. Consent decree of condemnation. Product ordered released under bond to be relabeled. (F. D. C. No. 4857. Sample No. 62052-E.)

On June 10, 1941, the United States attorney for the Northern District of Illinois filed a libel against 289 dozen bottles of papaya syrup at Chicago, Ill., alleging that the article had been shipped on or about February 25, 1941, by Tropical Fruit Products from St. Louis, Mo.; and charging that it was misbranded.

Analysis of a sample of the article, which was an opaque, yellow, syrupy liquid, showed that it consisted essentially of sugars, fruit acids, and orange and lemon oils, with the flavor of papaya. No active papain nor other proteolytic enzymes were found.

The article was alleged to be misbranded in that representations in the labeling that it would supply energy food which could be easily absorbed; that it would

promote health and build energy, thus making one feel more alive and full of pep; that it would reduce the absorption of poisonous toxins and stomach distress; that it was an alkalizer and body builder; that it would prevent kidney, liver, and stomach diseases and keep the skin clear; that it was an appropriate treatment for anemia, gastritis, indigestion, constipation, arthritis, rheumatism, ulcers, colitis, sinusitis, influenza, colds, dysentery and obesity; and that it would increase the stature of children, were false and misleading since it would not be efficacious for such purposes.

It also was alleged to be misbranded under the provisions of the law applicable to foods, as reported in F. N. J. No. 3647.

On June 24, 1941, C. O. Pinkard, claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond conditioned that it be relabeled under the supervision of ble to foods, as reported in F. N. J. No. 3647.

637. Misbranding of Magozone. U. S. v. 28 Packages of Magozone. Default decree of condemnation and destruction. (F. D. C. No. 4975. Sample No. 5176–E.)

On June 23, 1941, the United States attorney for the Southern District of Ohio filed a libel against 28 packages of Magozone at Cincinnati, Ohio, alleging that the article had been shipped on or about April 17, 1941, by the Eastern American Association for Oxygen Therapy from Bloomfield, N. J.; and charging that it was misbranded.

Analysis showed that the article consisted essentially of magnesium oxide and peroxide, and that it neither contained nor would produce ozone.

The article was alleged to be misbranded in that certain statements in the labeling which represented and implied that it would liberate ozone; that it would eliminate the cause of diseases, restore healthy blood, repair damage; that it would be efficacious in all ailments due to constipation and faulty assimilation, metabolism, and elimination which result in a gradual poisoning of the system, as well as those due to other poisonings of the body; that it was a general purifier for many ailments, gas, poisoning, etc.; that it would be of value in the treatment of nausea, gas in stomach or intestines, headache, dizziness, pressure upon the heart, biliousness; that it would be efficacious in the treatment of diarrhea and ulceration of the digestive tract; that it would purify the blood and lymph vessels and organs; that it would prevent the development of parasites; and that it would eliminate the causes of disease and restore lost health; and that another drug, namely, Calozone, would be efficacious in the correction of running bowels and in the treatment of pus or mucous formation, were false and misleading since the articles would not be efficacious for such purposes.

On August 7, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

638. Misbranding of rock candy crystals. U. S. v. 54 Boxes of Rock Candy Crystals. Default decree of condemnation. Product distributed to charitable institutions. (F. D. C. No. 6323. Sample No. 49823–E.)

Examination showed that this product consisted of coarse sucrose crystals.

On December 2, 1941, the United States attorney for the Western District of Louisiana filed a libel against 54 boxes, each containing 24 packages, of rock candy crystals at Shreveport, La., alleging that the article had been shipped in interstate commerce on or about October 30 and November 3, 1941, by Martin Candy Co. from Dallas, Tex.; and charging that it was misbranded.

The article was alleged to be misbranded (1) in that the following statements on the package were false and misleading: "Dissolve the Rock Candy Crystals In This Package In a Half Pint of the Best Old Rye Whiskey Such a Cordial Is a Cardinal Remedy for Coughs. Colds. And all Pulmonary Complaints. * * * A Most Excellent Tonic Recommended by Physicians," since the consensus of medical opinion does not support the representation that the article when used in the manner directed would be efficacious for the purposes recommended, and the labeling failed to reveal that fact; and (2) in that its container was so made and filled as to be misleading, since the packages were too large for the amount of crystals they contained and the crystals did not occupy a reasonable amount of the available space.

It also was alleged to be misbranded under the provisions of the law applicable to foods, as reported in F. N. J. No. 3639.

On February 16, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered disposed of as provided by law. It was distributed to charitable institutions.

639. **Misbranding of Santé. U. S. v. 16 Cases of Santé. Default decree of condemnation and destruction.** (F. D. C. No. 5089. Sample No. 29413–E.)

On July 9, 1941, the United States attorney for the Southern District of Indiana filed a libel against 16 cases of Santé at Evansville, Ind., alleging that the article had been shipped in interstate commerce on or about February 12, 1941, by Dr. W. B. Caldwell, Inc., from Monticello, Ill.; and charging that it was misbranded.

Analysis showed that the article was an alcoholic solution containing in each fluid ounce an iron compound representing approximately 150 milligrams of iron and 800 U. S. P. units of vitamin B_1 per fluid ounce.

The article was alleged to be misbranded in that statements in the labeling which represented and suggested that it was an appropriate treatment for nutritional anemia due to dietary deficiencies; that it was an efficacious treatment for pale, underweight women with poor appetite; that it would help the system get over the conditions following colds, grippe, flu; that it would increase personality and stamina, and would help develop the blood, improve the appetite and color and quiet the nerves; would promote assimilation of food and better sleep, and would increase weight; and that it was important to nerves, stomach, and bowels, were false and misleading since it would not be efficacious for such purposes.

On November 17, 1941, the claimant having withdrawn his appearance, judgment of condemnation was entered and the product was ordered destroyed.

640. **Misbranding of Vigor-Tex. U. S. v. 20 Cases and 6 Packages of Vigor-Tex (and 1 other seizure against Vigor-Tex). Default decree of condemnation and destruction.** (F. D. C. Nos. 4920, 4934. Sample Nos. 47447–E, 47456–E.)

On June 18 and 24, 1941, the United States attorney for the Northern District of Illinois filed libels against 20 cases, each containing 24 packages; 37 cases, each containing 12 packages; and 6 packages of Vigor-Tex at Chicago, Ill., alleging that the article had been shipped in interstate commerce by Kretschmer Corporation from Saginaw, Mich., on or about May 12 and 17, 1941; and charging that it was misbranded.

Examination of the article showed that it consisted of about 42 percent of wheat germ, the remainder consisting essentially of wheat bran and small amounts of starch.

It was alleged to be misbranded in that statements in the labeling which represented and suggested that it would be efficacious to build vitality, promote better health, provide the life principle needed for the functioning of all organs; that it would be efficacious to correct low spirits, discouragement, and tiredness, would strengthen the heart muscle and normalize the blood pressure; would cause children to thrive, grow in height and weight, and would improve their appetite and general health; that it would prevent sleeplessness, tiredness, poor heart action, fatigue, indigestion, and gray hair; that it was a preventive and appropriate treatment of constipation, arthritis, neuritis, colitis, colds, simple anemia and pernicious anemia, diabetes, skin blemishes, brittle nails, stomach ulcers, heart trouble, hardening of the arteries, high blood pressure, glandular deficiency, acidosis, underweight and overweight conditions, were false and misleading since it would not be efficacious for such purposes.

On October 1, 1941, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

641. **Misbranding of Polly Rich Wheat Germ. U. S. v. 219 Cans of Wheat Germ. Default decree of condemnation and destruction.** (F. D. C. No. 6362. Sample No. 83181–E.)

The labeling of this product bore false and misleading representations regarding its value as a source of certain vitamins and minerals and its efficacy in the treatment of diseases and abnormalities of the body.

On December 9, 1941, the United States attorney for the Eastern District of Louisiana filed a libel against 219 cans of wheat germ at New Orleans, La., alleging that the article had been shipped in interstate commerce on or about September 15, 16, and 24, 1941, by the Colonial Milling Co. from Nashville, Tenn.; and charging that it was misbranded. It was labeled in part: "Polly Rich Wheat Germ."

The article was alleged to be misbranded in that the following and similar statements in the labeling, (label) "Contains Vitamins A-B-E-G * * * Four level tablespoons of Wheat Germ contain about the average daily requirement of Vitamin B," and (circular entitled "Polly Rich Wheat Germ contains vitamins A-B-E-G," attached to retail package) "'Nature's Own Tonic in Its Pure Virgin Wholeness' * * * The heart or embryo of the grain of wheat is known as 'Wheat Germ'. It is one of the best known sources of Vitamin B (whole complex) and E and is a good source of Vitamin A. It contains iron, phosphorus, sodium, potassium, zinc, copper, manganese, calcium and magnesium, all of which are essential to our mineral economy, in forms which are easily assimilated. Wheat Germ is in truth 'Nature's own health tonic in its pure virgin wholeness,'" were false and misleading since they created the impression that wheat germ is a consequential source of vitamins A, B, E, and G and of the minerals iron, phosphorus, sodium, potassium, zinc, copper, manganese, calcium and magnesium; whereas, while wheat germ may be considered as a consequential source of vitamin B and phosphorus, the contribution to the dietary intake of the other vitamins and minerals contained in wheat germ is inconsequential. It was alleged to be misbranded further in that representations in the labeling that it was efficacious in the treatment of a wide variety of diseases and abnormalities of the body, such as secondary anemia, cataracts of the eye, sterility, and alcoholic diseases, were false and misleading since it would not be efficacious for such purposes.

It was also charged to be misbranded under the provisions of the law applicable to foods, as reported in notice of judgment F. N. J. No. 3222.

On March 25, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ALSO FAILING TO BEAR REQUIRED INGREDIENT STATEMENT

642. Misbranding of Diaplex. U. S. v. 97 Packages of Diaplex. Default decree of condemnation and destruction. (F. D. C. No. 5230. Sample No. 7684–E.)

The labeling of this product bore false and misleading representations regarding its efficacy in the treatment of diabetes. Furthermore, it was a drug but its label failed to bear the common or usual name of such drug.

On July 26, 1941, the United States attorney for the Southern District of California filed a libel against 97 packages of Diaplex at Santa Monica, Calif., alleging that the article had been shipped in interstate commerce on or about June 25, 1941, by Mrs. Alice Pierce from Wellington, Colo.; and charging that it was misbranded.

Analysis showed that the article consisted of the ground or shredded leaves and stems of a species of saltbush such as *Atriplex canescens*.

The article was alleged to be misbranded in that the following statements on the label, "Directions to doctors for those whose blood-sugar count tests 125 mgs. per 100 C. C. or over. Use four heaping tablespoons of Diaplex to the quart of water and * * * an adult should use two quarts of Diaplex tea daily and a child, one, for a period of nine to eighteen months. Diaplex * * * should never lower the blood-sugar below normal. Therefore a great amount is effective. Small doses are worthless for the diabetic. * * * Notice: Warning! persons using Diaplex with insulin should make the urine test daily, and as the pancreas increases its normal function, reduce the amount of insulin sufficiently to avoid insulin reaction. Only use enough insulin to take care of the surplus sugar reducing the amount of insulin from time to time sufficiently to avoid insulin reaction: But continue the use of Diaplex until you are well and strong," were false and misleading since they created the impression that it would be useful for reducing abnormally high blood-sugar content and as a treatment for diabetes; whereas it was not capable of accomplishing such results. It was alleged to be misbranded further in that it was a drug and its label failed to bear the common or usual name of such drug.

On September 8, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

643. Misbranding of Hicks' Quinine Hair Tonic. U. S. v. 5 1-Gallon Bottles and 6 8-Ounce Bottles of Hicks' Quinine Hair Tonic. Default decree of condemnation and destruction. (F. D. C. No. 6218. Sample No. 70127–E.)

The labeling of this product bore false and misleading representations regarding its efficacy in the conditions indicated hereinafter. The label also failed to bear an accurate statement of the quantity of the contents and the common or usual names of the active ingredients present.

On December 1, 1941, the United States attorney for the Western District of North Carolina filed a libel against the above-named product at Asheville, N. C., alleging that it had been shipped in interstate commerce on or about June 2, 1941, by J. A. Hicks from Jacksonville, Fla.; and charging that it was misbranded.

Analysis of a sample of the article showed that it consisted essentially of alcohol (approximately 61 percent by volume), salicylic acid (approximately 0.9 percent), quinine sulfate, water, and perfume materials.

The article was alleged to be misbranded (1) in that the statements on the label, "Quinine Hair Tonic, * * * for eczema, alapacia, dandruff, itching scalp. Will promote the growth of the hair," were false and misleading as applied to an article that does not act as a tonic for the hair and does not constitute an adequate treatment for the disease condition for which it was represented; (2) in that its label failed to bear an accurate statement of the quantity of the contents; and (3) in that the label failed to bear the common or usual names of the active ingredients.

On December 31, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

644. Misbranding of Respirine. U. S. v. 52 Dozen Bottles of Respirine. Default decree of condemnation and destruction. (F. D. C. No. 5303. Sample Nos. 40478-E, 69242-E.)

The labeling of this product bore false and misleading curative and therapeutic claims, and also failed to bear a statement of the quantity or proportion of belladonna alkaloids that it contained.

On July 31, 1941, the United States attorney for the Southern District of New York filed a libel against 52 dozen bottles of Respirine at New York, N. Y., alleging that the article had been shipped in interstate commerce prior to July 14, 1941, by Albert Laboratories, Inc., from Chicago, Ill., to Atlantic City, N. J., and that on or about July 14, 1941, it had been reshipped by the Atlantic City Wholesale Drug Co. from Atlantic City, N. J.; and charging that it was misbranded.

Analysis showed that it consisted essentially of sugar, water, ammonium chloride, ammonium carbonate, potassium nitrate, and alkaloidal plant drugs, including atropine and emetin-bearing drugs.

The article was alleged to be misbranded in that the following statements appearing in the labeling were false and misleading: "* * * is highly efficient in alleviating wheezing—sniffing choking attacks coughing spells and other respiratory irritations due to irritants in bronchial tubes, or—'Colds' * * * in severe cases. * * * to alleviate 'misery' resulting from such symptoms as: Coryza—sneezing—congested mucous membranes—wheezing—coughs—and other respiratory irritations due to irritants in bronchial tubes—or—to 'Colds.' * * * Sufferers From Asthma—Bronchitis Coughs (Resulting From Common Colds) Hay Fever Thank Their Lucky Stars They Discovered Respirine The Quick New Safe Way of Successfully Relieving Coughing Spells Choking Attacks Wheezing Spasms." It was alleged to be misbranded further in that the label failed to bear a statement of the quantity or proportion of belladonna alkaloids that it contained.

On September 10, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

VETERINARY REMEDIES

645. Misbranding of Sea-Clo-400-D. U. S. v. 2 Cans of Sea-Clo-400-D. Default decree of condemnation and destruction. (F. D. C. No. 6255. Sample No. 50347-E.)

This product was represented as a satisfactory substitute for poultry cod-liver oil, which representation was misleading. Spectro-photometric examination of a sample showed that the article contained approximately 400 U. S. P. units of vitamin A per gram; whereas the United States Pharmacopoeia requires that cod-liver oil contain at least 850 U. S. P. units of vitamin A per gram.

On November 21, 1941, the United States attorney for the District of Maryland filed a libel against the above-named product at Middleburg, Md., alleging that it had been shipped on or about September 13, 1941, by Seaboard Supply Co., Inc., from Philadelphia, Pa.; and charging that it was misbranded.

The article was alleged to be misbranded in that the following statements on the label, "Sea-Clo-400-D, Highly Fortified Cod Liver Oil in Dry Base. Directions: In place of each 4¾ lbs. straight 85 D oil use 1 lb. Sea-Clo-400-D. For

each 5 pints 85 D oil used replace with 1 lb. Sea–Clo–400–D. Turkeys: Use three times the amount recommended for poultry under average conditions. Ingredients: Fortified cod liver oil. When this product is packed it contains more than 1000 Units Vitamin 'A' per gram . . . due to uncertain stability of Vitamin 'A' from cod liver oil when added to feeds we are making no claim for it," were misleading since they gave the impression that it was a substitute for cod-liver oil and possessed essentially the same values when used in accordance with the directions for use; whereas it was not a substitute for cod-liver oil and did not contain essentially the same values when used in accordance with such directions since the proportion of vitamin A to vitamin D furnished when so used, was substantially less than that furnished by straight cod-liver oil.

The article also was alleged to be misbranded under the provisions of the law applicable to foods, as reported in F. N. J. No. 3453.

On January 3, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

646. Misbranding of Heberling's Colic and Bloat Compound and Heberling's Veterinary Liniment. U. S. v. 110 Dozen Bottles of Heberling's Colic and Bloat Compound and 99 Dozen Bottles of Heberling's Veterinary Liniment. Consent decree of condemnation. Products ordered released under bond to be relabeled. (F. D. C. No. 3610, 3611. Sample Nos. 39127–E, 39128–E.)

On or about January 3, 1941, the United States attorney for the Southern District of Illinois filed a libel against the above-named products at Bloomington, Ill., alleging that they had been shipped on or about September 2, 1939, and April 26, 1940, by the J. R. Watkins Co. from Winona, Minn.; and charging that they were misbranded.

Analyses of samples of the articles showed that the colic and bloat compound consisted essentially of ether, chloroform, small proportions of capsicum, and volatile oils including clove oil, sassafras oil, camphor, and turpentine; and that the liniment consisted essentially of small proportions of oil of tar, camphor, turpentine, and cresol, and crude petroleum.

The colic and bloat compound was alleged to be misbranded in that statements appearing in the labeling representing that it would give relief in the treatment of colic and bloat in horses and cattle were false and misleading since it would not be efficacious for such purposes.

The liniment was alleged to be misbranded in that statements in the labeling representing that it would be efficacious for the treatment of wounds, sores, lameness, swellings, callous parts, poll evil, and fistula, and that use of Heberling's Mineral-Tonic Supplement for Hogs, Mineral-Tonic Supplement for Stock, and Mineral-Tonic Supplement for Poultry would insure more profitable production of livestock, were false and misleading since the articles would not be efficacious for the purposes recommended.

On July 14, 1941, G. C. Heberling, Bloomington, Ill., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the products were ordered released under bond conditioned that they be relabeled under the supervision of the Food and Drug Administration.

647. Misbranding of Poul-Tre-Tone and Pep-O-Tone. U. S. v. Gliatta Laboratories, Inc. Plea of guilty. Fine, $100. (F. D. C. No. 2877. Sample Nos. 15239–E, 15240–E.)

The labeling of these veterinary products bore false and misleading claims regarding their efficacy in the conditions indicated hereinafter.

On January 30, 1941, the United States attorney for the Eastern District of Missouri filed an information against Gliatta Laboratories, Inc., St. Charles, Mo., alleging shipment on or about March 21, 1940, from the State of Missouri into the State of Illinois of quantities of Poul-Tre-Tone and Pep-O-Tone which were misbranded.

Analysis of a sample of Poul-Tre-Tone showed that it consisted essentially of calcium phosphate, calcium carbonate, magnesium sulfate, compounds of iron, sodium, and potassium, and plant material including tobacco and kamala. Analysis of a sample of Pep-O-Tone showed that it consisted of small proportions of copper sulfate (0.81 percent), iron sulfate, compounds of zinc, sodium and potassium, creosote, and water, flavored with oil of cloves and colored with a red dye.

The Poul-Tre-Tone was alleged to be misbranded in that statements in the labeling which represented that it was efficacious for the treatment of all common known poultry diseases; would be efficacious to expel worms and destroy germs; would prevent weakness, bowel trouble, and disorders like pip

or other diseases in poultry; and would be efficacious to produce the beneficial effects implied by the expression "It Builds" were false and misleading, since it would not be efficacious for such purposes.

The Pep-O-Tone was alleged to be misbranded in that statements in the labeling which represented that it would be efficacious in the treatment of bronchial and pneumonic conditions, diarrhea in chicks, coccidiosis, fowl cholera, small worms, roup, and all common diseases of baby chicks; would tone and build up baby chicks and prevent disease; and would prevent disease if used at all times were false and misleading, since it would not be efficacious for such purposes. It was alleged to be misbranded further in that the statement "Copper Sulphate 3%," borne on the label, was false and misleading, since it contained not more than 0.81 percent of copper sulfate.

On May 6, 1941, a plea of guilty was entered on behalf of the defendant and the court imposed a fine of $100.

648. Misbranding of N–K Capsules. U. S. v. 2 Cases of N–K Capsules Adult Size and 4 Cases of N–K Capsules Chick and Pullet Size. Decree of condemnation and destruction. (F. D. C. No. 2650. Sample Nos. 24368–E, 24369–E.)

On August 22, 1940, the United States attorney for the District of New Jersey filed a libel against the above-named products at Vineland, N. J., alleging that they had been shipped on or about May 22, June 11, and July 12 and 16, 1940, by Pratt Food Co. from Philadelphia, Pa.; and charging that they were misbranded.

Analyses of samples of the articles showed that they consisted essentially of nicotine (0.8 grain per capsule in the adult size and 0.35 grain per capsule in the chick size), sulfur, aloin, kamala, strychnine, burnt sienna, talc, sugar, carbon, a magnesium compound, and stearates.

The adult-sized capsules were alleged to be misbranded in that their labeling bore representations that they were efficacious in the expulsion or removal from chickens of the following species of tapeworms: *R. Tetragona*, *D. cesticillus*, *D. echinobothrida*, and *M. lucida*, which representations were false and misleading since they would not be efficacious in the expulsion or removal of any species of tapeworms from chickens.

The chick-sized capsules were alleged to be misbranded in that their labeling bore representations that they were efficacious in the expulsion or removal from chickens of the following species of tapeworms: *R. tetragona*, *D. cesticillus*, *D. echionobothrida*, and *M. lucida*, and in the expulsion or removal of large roundworms, which representations were false and misleading since they would not be efficacious in the expulsion or removal of any species of tapeworms, and because of the small amount of nicotine present they would not be efficacious in the expulsion or removal of large roundworms.

On October 11, 1941, Pratt Food Co., intervening defendant, having stated that it had ceased manufacturing and marketing these or similar products and that it had no intention of doing so in the future, and having made application for permission to withdraw exceptions to the libel and petition for intervention previously filed in its behalf, the court granted the application to withdraw the exceptions to the libel, and entered a decree of condemnation and destruction.

649. Misbranding of Lipscomb's Sungold Egg Pellets. U. S. v. 17 Bags of Lipscomb's Sungold Egg Pellets. Default decree of condemnation and destruction. (F. D. C. No. 5014. Sample No. 67195–E.)

The labeling of this product bore false and misleading representations regarding its efficacy in the control and treatment of worms in poultry.

On June 27, 1941, the United States attorney for the Eastern District of Arkansas filed a libel against 17 bags of the above-named product at Hoxie, Ark., alleging that the article had been shipped in interstate commerce on or about May 8, 1941, by the Lipscomb Grain & Feed [Seed] Co. from Springfield, Mo.; and charging that it was misbranded.

Analysis showed that the article consisted of brown, cylindrical pellets containing chiefly ground plant material, together with small amounts of nitrogenous material and mineral matter, including calcium, iron, sodium, magnesium, manganese, sulfur, carbonate, and a minute quantity of nicotine.

The article was alleged to be misbranded in that statements in the labeling which represented that it would be efficacious in the treatment and control of worms; that it would provide a "wall of protection" against worms getting started; that it was an effective agent with which to combat all kinds of poultry worms in all stages of their life cycle; that it was equally valuable for chickens, turkeys, ducks, and geese; that it would protect fowls from

contracting such worms as tapeworms and many kinds of worms that cannot successfully be removed once they become fixed; that it would remove roundworms and caeca worms; that it would attack the life in the worm egg while in the fowl's intestine; and would combat little worms just hatched or released from intermediate hosts, were false and misleading since it would not be efficacious for such purposes.

On August 4, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

650. Misbranding of Walko Tablets. U. S. v. 4,968 Boxes and 1,008 Boxes of Walko Tablets. Default decree of condemnation and destruction. (F. D. C. No. 4547. Sample Nos. 58475–E, 58476–E.)

The labeling of this product bore false and misleading representations regarding its efficacy (also the efficacy of another drug) in the treatment and control of certain poultry diseases.

On May 2, 1941, the United States attorney for the District of Minnesota filed a libel against 4,968 boxes, each containing 100 tablets, and 1,008 boxes, each containing 250 tablets, of Walko Tablets at Minneapolis, Minn., alleging that the article had been shipped in interstate commerce on or about February 21, 1941, by the Walker Remedy Co. from Waterloo, Iowa; and charging that it was misbranded.

Analysis showed that it consisted essentially of potassium permanganate, boric acid, and calcium sulfate.

The article was alleged to be misbranded in that statements in the labeling which represented that it would be efficacious in the treatment of simple catarrh, sneezing and wheezing, simple diarrhea, coccidiosis, nutritional diseases, rickets, and polyneuritis; that it would keep the entire digestive tract of poultry in a normal and healthy condition, would prevent digestive disturbances among baby chicks; that it was a control measure during infectious diseases, and would be efficacious for the swellings of roup in the head and simple catarrh among older birds; that it would prevent poultry losses; that it would be effective to control bacillary white diarrhea (Pullorum Disease), would aid in the control of infectious diseases among chickens, turkeys, geese, ducks, squabs, pheasants, parrots, and canaries, and would enable chicks to develop more quickly and feather earlier; and that another drug, namely Walko Tonix, would promote digestion, stimulate the liver and other functions, and would bring birds back to normal and keep them in the pink of condition, thus insuring greater egg production and would make feathers smooth and glossy, combs red, and would start hens laying, were false and misleading since the articles would not be efficacious for such purposes.

On July 9, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

MOLESKIN PLASTER IN DECEPTIVE CONTAINERS

651. Misbranding of moleskin adhesive plaster. U. S. v. 23 Dozen and 22½ Dozen Packages of Moleskin Adhesive Plaster. Consent decree of condemnation. Product ordered delivered to a local hospital. (F. D. C. No. 2477. Sample Nos. 33712–E to 33716–E, incl.)

These plasters were contained in packages that were much larger than was necessary. At least twice the length of plaster could easily have been placed in the containers.

On August 5, 1940, the United States attorney for the Southern District of New York filed a libel against 45½ dozen retail packages of Moleskin plasters at New York, N. Y., alleging that the article had been shipped in interstate commerce within the period from on or about January 19 to on or about March 1, 1940, by Bauer & Black Division of the Kendall Company from Chicago, Ill.; and charging that it was misbranded. The articles were labeled in part: "Moleskin Blue-Jay Zinc Oxide Adhesive 7 Inches x ½ Yard"; or "Adhesive Plaster Moleskin Zinc Oxide 7 Inches x 1 Yard."

The articles were alleged to be misbranded in that their containers were so made, formed, or filled as to be misleading.

On October 6, 1941, the Kendall Co., claimant, having filed an amended answer admitting the allegations of the libel and consenting to the entry of the decree, judgment of condemnation was entered and the product was ordered delivered to a local hospital.

NONSTERILE SURGICAL DRESSINGS

652. Misbranding of Emergency First Aid Cabinet No. 20 and refills. U. S. v. 94 Kits and 83 Refills. Default decree of forfeiture and destruction. (F. D. C. No. 5849. Sample No. 58056–E.)

On September 30, 1941, the United States attorney for the Western District of Wisconsin filed a libel against the above-named product at Eau Claire, Wis., alleging that the article had been shipped on or about August 16, 1940, and March 31, 1941, by the American First Aid Co. from Brooklyn, N. Y.; and charging that it was misbranded.

Examination showed that the kits and refills contained, among other things, absorbent cotton, gauze pads, adhesive tape, a tube of burn ointment, and a bottle each of boric acid, mercurochrome, and aromatic spirits of ammonia. The burn ointment was not antiseptic as claimed on the label, and the boric acid was a solution of approximately 1.3 percent concentration.

The kits and refills were alleged to be misbranded: (1) In that the carton containing the absorbent cotton bore the following statement, "Sterilized and Surgically Clean Highest Quality," whereas the absorbent cotton was contaminated with aerobic and anaerobic micro-organisms. (2) In that the carton containing burn ointment bore the statement "Antiseptic," whereas the burn ointment was not antiseptic. (3) In that the label of the boric acid bore the following statement, "Antiseptic * * * Eye Wash (4% aqueous solution)," whereas the boric acid was not a 4 percent solution but was a solution of approximately 1.3 percent concentration, and it was not antiseptic. (4) In that the outside container did not bear a statement of the common or usual names of the active ingredients in the burn ointment, boric acid, and the mercurochrome. (5) In that the carton and label of the burn ointment did not contain the common or usual names of the active ingredients. (6) In that the retail container did not bear an accurate statement of the quantity of the contents. (7) In that the labels for the absorbent cotton, gauze pads, wood applicators, and the carton for the burn ointment did not bear the name and address of the manufacturer, packer, or distributor.

On October 29, 1941, no claimant having appeared, judgment of forfeiture was entered and the product was ordered destroyed.

653. Misbranding of first aid kits and gauze bandage. U. S. v. 138 First Aid Kits and 100 Boxes and 12 Gross Packages of Gauze Bandage. Default decrees of condemnation and destruction. (F. D. C. Nos. 3815, 6018, 6045. Sample Nos. 24588–E, 51597–E, 51598–E.)

The gauze bandage in all of these shipments was not sterile, and the metal containers of the first aid kits failed to bear a list of the various items in the kit and the quantity of each.

On February 13 and October 14 and 20, 1941, the United States attorneys for the Eastern District of Pennsylvania and the District of Massachusetts filed libels against 138 first aid kits at Philadelphia, Pa., and 100 boxes and 12 gross packages of gauze bandage at Boston, Mass., alleging that the articles had been shipped on or about January 15 and September 17, 1941, by American White Cross Laboratories from New Rochelle, N. Y.; and charging that it was misbranded. The articles were labeled in part: "White Cross All Purpose First Aid Kit"; "Gauze Bandage 1 in. 10 yds Hospital Bandage"; and "Sanitized Clinical Gauze Bandage."

The first aid kits were alleged to be misbranded (1) in that statements on the envelope containing the bandage strips, "Ideal for bruises, cuts and Blisters" and "Emergency Bandage," were false and misleading as applied to an article which was not sterile and therefore was not ideal for use on bruises, cuts and blisters or for emergency bandage purposes; (2) in that the statements metal container) "All purpose First Aid Kit" and "Be Prepared" and the designs of a surgeon and nurse were false and misleading as applied to an article which contained non-sterile bandage strips; and (3) in that the metal container of the retail package failed to bear on its label a statement of the quantity of contents, since it did not list the various items in the kit and the quantity of each contained in the package.

A portion of the gauze bandage was alleged to be misbranded in that the following statements on the carton, "Self Sterilizing Sanitized * * * Clinical * * * Actively Antiseptic This Gauze Bandage Has Been Protected With The Process Sanitized * * * It Is Actively Antiseptic and Self Sterilizing in its effect," were false and misleading as applied to an article that was not

self sterilizing nor antiseptic, but was contaminated with viable micro-organisms. The remainder was alleged to be misbranded in that the following statements and designs appearing on the carton, "Prepared under the most sanitary and scientific conditions * * * Hospital Bandage [pictures of doctor and nurse]," which implied that it was sterile, were false and misleading as applied to an article that was contaminated with viable micro-organisms.

On September 29, 1941, and January 19, 1942, no claimant having appeared, judgments of condemnation were entered and the products were ordered destroyed.

654. Adulteration and misbranding of gauze bandages. U. S. v. 500 Dozen Gauze Bandages (and 1 other seizure of gauze bandages). Default decrees of condemnation and destruction. (F. D. C. Nos. 4371, 4868. Sample Nos. 22309–E, 50831–E.)

This product had been shipped in interstate commerce and was in interstate commerce at the time of examination, at which time it was found to be contaminated with viable micro-organisms. It was packaged in ordinary type carton without protective wrapping such as would be necessary to prevent contamination with bacteria. The carton was one-third larger than was necessary to contain the bandages.

On April 16 and June 4, 1941, the United States attorneys for the Northern District of California and the District of Maryland filed libels against 500 dozen gauze bandages at San Francisco, Calif., and 10 cartons each containing 1 dozen packages of gauze bandages at Baltimore, Md. Subsequently the libel filed in Northern California was amended. The libels alleged that the article had been shipped in interstate commerce within the period from on or about September 28, 1940, to on or about April 14, 1941, by the Forest City Rubber Co. from Cleveland, Ohio; and charged that it was adulterated and misbranded.

The article was alleged to be adulterated in that its quality fell below that which it purported or was represented to possess, since the statement "Sentinel Gauze Bandage" and the design of a soldier on the carton carried the implication, in the absence of a specific disclaimer on the carton, that the article was sterile and was suitable for use upon open cuts, wounds, etc.; whereas it was not sterile, and was not suitable for such use.

It was alleged to be misbranded in that the statement "Sentinel Gauze Bandage" and the design of a soldier were false and misleading as applied to a bandage which was not sterile, in the absence of a specific statement of the material fact that the article was not sterile and was not suitable for use upon broken skin. It was alleged to be misbranded further in that the difficultly legible statement on the carton "This product was thoroughly sterilized during manufacture and cleanly packaged, but continued sterility can not be guaranteed" was misleading since it created the impression that reasonable precautions were taken in the preparation and packaging of the article, to assure its continued sterility; whereas such precautions were not taken.

It was alleged to be misbranded further in that its package was so filled as to be misleading in that the retail carton was approximately one-third larger than necessary to contain the bandage.

On July 9 and August 5, 1941, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

PROPHYLACTICS

655. Adulteration and misbranding of prophylactics. U. S. v. 5½ Gross of Prophylactics. Default decree of condemnation and destruction. (F. D. C. No. 5197. Sample No. 47479–E.)

This product was defective because it contained holes.

On July 25, 1941, the United States attorney for the Northern District of Illinois filed a libel against 5½ gross of prophylactics at Chicago, Ill., alleging that the article had been shipped in interstate commerce on or about June 2, 1941, by the International Distributors from Memphis, Tenn.; and charging that it was adulterated and misbranded. It was contained in unlabeled packages.

The article was alleged to be adulterated in that its quality fell below that which it purported or was represented to possess. It was alleged to be misbranded in that it did not bear a label containing the name and address of the manufacturer, packer, or distributor, nor did it bear a label containing an accurate statement of the quantity of the contents.

On October 15, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

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PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] Contains an opinion of the court.

U. S. GOVERNMENT PRINTING OFFICE: 1943

D. D. N. J., F. D. C. 656–700 Issued February 1943

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

656–700

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States District Courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

WATSON B. MILLER, *Acting Administrator, Federal Security Agency.*

Washington, D. C. December 21, 1942.

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DRUGS AND DEVICES ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

656. Adulteration and misbranding of sulfathiazole. U. S. v. Winthrop Chemical Co., Inc. Plea of guilty. Fine, $15,800. (F. D. C. No. 5502. Sample Nos. 5579–E, 14283–E, 14292–E, 29186–E, 29394–E, 36299–E, 38674–E, 39717–E, 39718–E, 39753–E, 40580–E, 40581–E, 40619–E, 40620–E, 49234–E, 50523–E, 50527–E, 50949–E, 51120–E, 51122–E, 51124–E, 51501–E, 51508–E, 57062–E to 57065–E, incl., 57581–E, 57644–E, 57727–E, 57728–E, 58427–E, 69305–E.)

This product was represented to consist of 0.5 gram, or 7.72 grain, sulfathiazole tablets, but in 12 of the 14 shipments there were tablets which contained little or no sulfathiazole but which did contain phenobarbital in amounts varying from approximately 4¼ grains to 6 grains. Two of the shipments contained tablets containing approximately the declared amount of sulfathiazole and small amounts of phenobarbital.

On December 17, 1941, the United States attorney for the Southern District of New York filed an information against Winthrop Chemical Co., Inc., a corporation having its principal place of business at New York, N. Y., alleging shipment within the period from on or about August 3, 1940, to on or about January 2, 1941, from the State of New York into the District of Columbia and into the States of Florida, Iowa, Kentucky, Massachusetts, Minnesota, Missouri, Pennsylvania, and Virginia of quantities of sulfathiazole tablets that were adulterated and misbranded.

Portions of the drug when examined by this agency were in their original labeled bottles. The remaining lots had been removed from their original bottles and, at the time of such examination, bore no labeling.

The article in all shipments was alleged to be adulterated: (1) In that its strength differed from and its purity and quality fell below that which it pur-

ported and was represented to possess since it purported to be and was represented as tablets each of which contained 0.5 gram, or 7.72 grains, of sulfathiazole and no other physiologically active ingredient; whereas in 12 of the 14 shipments there were tablets which contained inconsequential amounts of, or no, sulfathiazole but did contain phenobarbital in amounts varying from 4.23 grains to 6.03 grains per tablet, and in the remaining 2 shipments there were tablets containing phenobarbital in amounts varying from 0.03 grain to 0.24 grain. (2) (12 of the 14 shipments.) In that tablets which contained inconsequential amounts of, or no, sulfathiazole but did contain phenobarbital in amounts varying from 4.23 grains to 6.03 grains per tablet, or (remaining 2 shipments) tablets which contained phenobarbital in amounts varying from 0.03 grain to 0.24 grain, had been substituted in part for tablets containing ½ gram (7.72 grain) of sulfathiazole and no other physiologically active ingredient.

Misbranding was alleged with respect to all or part of the tablets (in 6 shipments), which were in their original labeled containers, in that they would be dangerous to health when used in the dosage or with the frequency or duration suggested in the labeling, i. e., "0.5 Gm. (7.72 grains) Sulfathiazole Winthrop (2-sulfanilamido thiazole) * * * Caution: To be used only by or under the direct supervision of a physician," since the statement suggested administration of the drug in dosages appropriate for the administration of 0.5 gram (7.72 grain) tablets of sulfathiazole, whereas if administered in dosages appropriate for the administration of sulfathiazole tablets of such strength, they would be dangerous to health because of admixture therewith of tablets containing phenobarbital in amounts varying from 0.274 gram (4.23 grains) to 0.391 gram (6.03 grains) per tablet.

All shipments of the article were alleged to be misbranded in that a number of tablets containing phenobarbital, a physiologically active ingredient, in amounts hereinbefore stated, had been offered for sale under the name of another drug, namely, "Tablets 0.5 Gm. (7.72 grains) Sulfathiazole," or "Sulfathiazole Tabs [or "Tablets"] 0.5 Gm."

Portions of the article, i. e., those which were in their original labeled containers were alleged to be misbranded further: (1) In that the statement on the label, "Tablets 0.5 Gm. (7.72 grains) Sulfathiazole," was false and misleading since it represented and suggested that the drug consisted of tablets each containing 0.5 gram (7.72 grains) of sulfathiazole and no other physiologically active ingredient; whereas it consisted of tablets some of which contained an inconsequential amount of, or no, sulfathiazole, but did contain phenobarbital in amounts varying from 4.23 grains to 6.03 grains per tablet. (2) In that the labeling was misleading since it failed to reveal the fact material with respect to the consequences which might result from its use under conditions prescribed in the labeling or under such conditions of use as are customary or usual, i. e., the fact that there was present in said drug a number of tablets that contained phenobarbital, a physiologically active ingredient, in amounts varying from 0.274 gram (4.23 grains) to 0.391 gram (6.03 grains) per tablet, and that when administered in dosages in which sulfathiazole is customarily administered it would produce phenobarbital poisoning.

On January 28, 1942, the defendant entered a plea of guilty and the court imposed a fine of $1,000 on each of the counts charging that the product was dangerous to health, and a fine of $350 on each of the additional 28 counts, totaling $15,800.

657. Adulteration and misbranding of Interferin. U. S. v. 3 Tubes and 3 Boxes each containing 1 Tube of Interferin. Default decrees of condemnation and destruction. (F. D. C. Nos. 6320, 6741. Sample Nos. 14766–E, 54630–E.)

This product would be dangerous to health when use as recommended or suggested in its labeling.

On December 1, 1941, and January 20, 1942, the United States attorney for the Eastern District of Pennsylvania filed libels against the above-named drug product at Philadelphia, Pa., alleging that the article had been shipped in interstate commerce on or about November 3 and 27, 1941, by the Keefer Laboratories from Chicago, Ill.: and charging that it was misbranded and that a portion was also adulterated.

Analysis showed that the article consisted essentially of potassium soap (approximately 11.3 percent), sodium soap (approximately 12.5 percent), potassium iodide (approximately 6 percent), benzoic acid (0.4 percent), fats and/or oils (0.4 percent), alcohol, and water.

The article in one of the shipments was alleged to be adulterated in that its purity and quality fell below that which it purported to possess since it was offered for use by injection into the uterus thereby implying that it was sterile; whereas it was not sterile but was contaminated with viable bacteria of a disease-producing type.

The article in the said shipment was alleged to be misbranded in that it was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the leaflet enclosed in the retail carton: "Attach uterine canule to tube and insert through the cervical canal approximately 2 inches into the uterus so that the tip of the canule rests in the cavum uteri. Now slowly inject Interferin, slightly moving the canule in different directions so that the tip of the canule will not press against the uterine tissue wall. Allow three minutes intermission if the patient is restless; a complete instillation should require about ten minutes. Dosis inject one third (⅓) of the tube in cases of pregnancy up to two months; a half (½) in three month cases; a full tube in four month cases; still later cases, 1½ tubes. Generally speaking a little more Interferin will produce a quicker expulsion of the fetus." The said shipment was alleged to be misbranded further in that statements in the labeling which represented that the article had been successfully on the market since 1933 and had proved its value in more than 5,000 cases without a single fatality known; that it had been developed after extensive research; that it offered very definite advantages over old methods; and that it was efficacious and appropriate for the following therapeutic group indications, "A. Dead fetus, mole, missed abortion. B. Living fetus. 1) Ovum diseases. 2) Pregnancy toxemias. 3) Complications at labor. 4) Genital tract diseases. 5) Systematic diseases. T. B. of the lungs, cardiac, kidney, blood, skin, syphilis. 6) Endocrine disorders. 7) Organic and functional nervous system diseases, intractable vomiting. 8) Special organ diseases, eye, blindness, ear. 9) Unclassified diseases, column fractures, caries. 10) Rape, incest. 11) Eugenic factors, heredity diseases, insanity, epilepsy, in which in addition to abortion sterilization is indicated. 12) Social economic indications. Illegitimacy, desertion, widowhood, overburdened impoverished physical depleted mothers"; and that it was effective and humane were false and misleading since they created the impression that it was a safe and appropriate medicament for effecting abortion; whereas it was not but was a dangerous drug. The said shipment was alleged to be misbranded further in that the statements, "The placenta is usually expelled a few minutes after the fetus," "Severe hemorrhages are very rarely observed after the use of Interferin," "the Interferin method is positively superior to dilation and curettage in cases of gravidity from two and a half to six months," were false and misleading since the placenta would not usually be expelled a few minutes after the fetus, severe hemorrhages would frequently occur after use of the article, and its use was not superior to dilation and curettage in such cases.

The article in the remaining shipment was alleged to be misbranded in that the name "Interferin" which had become impregnated with the meaning that the article was designed for introduction into the uterine cavity for the purpose of interfering with the normal progress of pregnancy, was false and misleading since the name represented and suggested that the article was safe and appropriate for interfering with the normal progress of pregnancy; whereas it was not safe or appropriate for such use but was unsafe and dangerous and capable of producing serious or even fatal consequences. It was alleged to be misbranded further in that its label failed to bear adequate directions for use since there were no adequate directions for the use above referred to.

On January 5 and February 16, 1942, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

658. Misbranding of Voltamp Battery No. 7. U. S. v. 1 Voltamp Battery No. 7. Default decree of condemnation. Product ordered delivered to Government. (F. D. C. No. 4822. Sample No. 69056–E.)

This device consisted of a case containing batteries, an electric coil, and attachments for applying electric current to the body. It was accompanied by a circular in which it was recommended for use in conditions involving paralysis and would be dangerous to health when used in such conditions. The circular also bore false and misleading claims regarding its efficacy in an enormous number of disease conditions.

On May 24, 1941, the United States attorney for the Northern District of New York filed a libel against one Voltamp Battery No. 7 at Schenectady, N. Y., alleg-

ing that the article had been shipped in interstate commerce on or about April 25, 1941, by the Voltamp Electric Manufacturing Co. from Baltimore, Md.; and charging that it was misbranded.

The article was alleged to be misbranded in that it would be dangerous to health when used with the frequency or duration prescribed, recommended, or suggested in the labeling for the following diseases: Amaurosis; aphasia, apoplexy, atrophy and non-development, muscular atrophy, backache, lame back, lameness, Bell's palsy, paralysis of bladder; blindness; cramps in bowels, catalepsy, trance; cramps, myalgia, cramps in muscles; general debility; difficulty of speech, dysphagia; paralysis of eye muscles, facial paralysis, fainting, syncope; hemiplegia; infantile paralysis, poliomyelitis; soreness, tired feeling; languor, listlessness, ennui; lockjaw, tetanus; loss of sensation, loss of voice, aphonia; meningitis, spinal meningitis; muscular contractions; neuralgia, sciatica, tic douloureaux; neuralgia of scalp; neuritis; numbness, general pain, shaking palsy, facial paralysis, paraplegia, throat paralysis, ptosis, falling of the eyelids; facial spasm, spasm of eyelid; vertigo, dizziness.

It was alleged to be misbranded further in that statements in the labeling which represented that it would be efficacious in the treatment of the above-named and the following disease conditions—pendulous abdomen; abscess, boils, furuncles, inflammation; alopecia, baldness, falling hair, dandruff, seborrhea sicca, other troubles of the scalp, acne, blackheads, comedones, pimples, chloasma, eczema, herpes zoster, shingles, hives, urticaria, nettle rash, itch, face wrinkles, amblyopia, failing sight, blindness, cataract, conjunctivitis, inflammation of eyes, spasm of eyelid, paralysis of eye muscles; amenorrhea, retention of the menses, dysmenorrhea, painful menstruation, menorrhagia, excessive menstruation, falling of the womb, prolapsus uteri, ulceration or inflammation of uterus; anemia, poverty of the blood, chlorosis; aphonia, hoarseness, stammering; paralysis; ascites, dropsy, asphyxia, asthma, hay fever; atrophy and non-development, soreness, lumbago; poor circulation of blood, cold feet, cold extremities, corns, bunions, irritable bladder, cystitis, urinary calculus, enlarged prostate, prostatitis, spasm of bladder, stone in the bladder, hyperaesthesia urethra, retention of urine, incontinence of urine; brain fag, cephalalgia, headache, headache accompanied by distress in the region of the stomach, liver and bowels, hypochondriasis and melancholia, hysteria, nervousness, insomnia, sleeplessness, tired feeling, migraine, nerves, neurasthenia; Bright's disease, kidney disorders; catarrhal jaundice, liver spots, cirrhosis of the liver, congestion of the liver, jaundice, hardening of the liver, torpid liver, liver troubles; cholera morbus, colic, nausea, sea sickness, constipation, enteralgia, cramps in bowels, chronic diarrhea, dysentery, flatulence, gastralgia, pain in the stomach, gastritis, indigestion, dyspepsia, loss of appetite, hysterical vomiting, vomiting of pregnancy, chorea, St. Vitus' dance, dysphagia, dizziness, vertigo; cold in the head, coryza, catarrh; consumption, coughs, croup, bronchitis, pleurisy; myalgia, cramps in muscles, crick in the neck, wry neck, torticollis; deafness, earache; diabetes; diphtheria; seminal emissions; spermatorrhea, functional sexual impotence, loss of vitality of the organs; enlarged glands, glandular tumors; epilepsy, catalepsy, trance; exophthalmic goiter; fever; frostbite, chillblains; hemorrhoids, piles, rectal prolapsus; hernia, rupture; persistent hiccough; enlarged, sprained joints, rheumatism, sprains, stiff joints, weak ankles, gout; lockjaw, tetanus; locomotor ataxia; malaria, ague, enlarged spleen; nose bleed, epistaxis; obesity; quinsy, sore throat, tonsillitis, enlarged tonsils; sunstroke; toothache, dontalgia; varicocele, varicose veins; whooping cough, pertussis; that it possessed a wonderful power to alleviate pain, cure disease, and save life; that it would increase the supply of mother's milk; would relieve afterpains, remove superflous hair, and rid one of all kinds of skin blemishes, that it would produce local anesthesia, would develop the bust and other shrunken parts, and would relieve constipation permanently, were false and misleading, since the device would not be efficacious for the purposes recommended.

On July 31, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered delivered to the Food and Drug Administration.

659. Misbranding of No. 48511–C Tablets and Goodwin's Laxative Cold Tablets. U. S. v. 81,600 No. 48511–C Tablets in bulk containers and 6,330 Packages of Goodwin's Laxative Cold Tablets. Consent decree of condemnation. Product ordered released under bond to be repackaged and relabeled. (F. D. C. No. 4883. Sample Nos. 50244–E, 50245–E.)

This case covered shipments of tablets in bulk containers, a portion of which had been repackaged and relabeled "Goodwin's Laxative Cold Tablets" by the con-

signee. The repackaged tablets would be dangerous to health when used according to directions. The labeling of both lots of tablets failed to bear adequate warning statements and satisfactory ingredient statements. Furthermore, the labeling of the bulk tablets failed to bear directions for use, and that of the repackaged tablets also bore false and misleading therapeutic claims.

On June 7, 1941, the United States attorney for the District of Maryland filed a libel against the above-named products at Baltimore, Md., alleging that they had been shipped on or about February 24 and 26 and March 4 and 10, 1941, by Sharp & Dohme from Philadelphia, Pa., and that having been so shipped, they remained in interstate commerce on the premises of the Read Drug & Chemical Co. at Baltimore, Md.; and charging that they were misbranded. The bulk tablets were labeled in part: (Container) "Sharp & Dohme Philadelphia, Pa. * * * No. 48511-C Made for Read Drug & Chemical Co. Baltimore, Md."

Analyses of samples taken from the bulk containers and the retail cartons showed that each tablet contained acetanilid (approximately 2 grains), quinine sulfate (¼ grain), podophyllin, capsicum, and belladonna extract.

The repackaged tablets were alleged to be misbranded: (1) In that they would be dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the labeling, namely, "Adults: 1 tablet every 4 hours until bowels move freely, then 1 tablet 2 or 3 times daily," since if taken in accordance with such directions they might result in the patient's ingesting amounts of acetanilid that would be dangerous to health. (2) In that the name "Goodwin's Laxative Cold Tablets" and the statements "Effective in the Treatment of Colds. Relieves the Feverish Condition which Accompany Colds," and "Keeps the Bowels Active," appearing in the labeling, were false and misleading since they gave the impression that the article was an effective treatment for colds; whereas it was not an effective treatment for colds and would not fulfill the promises of benefit made and implied by such statements. (3) In that a quantity of belladonna alkaloids was present in the article and the labeling did not bear a statement of the quantity or proportion of the belladonna alkaloids present.

Both lots of tablets were alleged to be misbranded in that the labeling did not bear adequate warnings against use in those pathological conditions or by children where their use might be dangerous to health and against unsafe dosage and duration of administration, in such manner and form, as are necessary for the protection of users, since said labeling bore no warnings that their use should be discontinued if a skin rash appeared; that they should be used cautiously if dryness of the throat occurred: that their use should be discontinued if rapid pulse or blurring of the vision resulted; that the preparation should not be taken by children; that frequent or continued use might be dangerous to health by causing serious blood disturbances, anemia, collapse, or dependence on the drug; that the preparation should not be taken by elderly people except on competent advice; that frequent use of the preparation might lead to dependence upon laxatives to move the bowels; and (bulk tablets only) since said labeling did not carry a warning against use of the article in the presence of abdominal pain, nausea, vomiting, or other symtoms of appendicitis.

The bulk tablets were alleged to be misbranded further (1) in that the label failed to bear adequate directions for use since it did not bear any directions for use; and (2) in that the labeling did not bear the common or usual name of each active ingredient, namely, acetanilid, quinine sulfate, podophyllin, capsicum, and belladonna extract, and in that it did not bear a statement of the quantity or proportion of acetanilid and belladonna extracts.

On August 6, 1941, the Read Drug & Chemical Co., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond conditioned that it be repackaged and relabeled under the supervision of the Food and Drug Administration.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS[1]

660. Misbranding of acetylsalicylic acid and colchicine compound capsules. U. S. v. Sam Frank Drug Co. Plea of guilty. Fine, $10. (F. D. C. 6430. Sample No. 65040-E).

In addition to failure to bear adequate warning statements, the label of this product failed to bear the required ingredient statement.

On March 13, 1942, the United States attorney for the District of Colorado filed an information against the Sam Frank Drug Co., a corporation at Denver,

[1] See also Nos. 657, 659.

Colo., alleging that within the period from on or about February 13 to on or about May 8, 1941, the defendant had repacked and relabeled quantities of the above-named product while it was being held for sale after shipment in interstate commerce, which acts by the defendant resulted in misbranding of said drug. At the time of shipment the product was labeled: "5000 Capsules Acetylsalicylic Acid and Colchicine Compound (Formerly Called Roomatoan) Brown. Each capsule contains: Acetylsalicylic Acid . . . 5 grs. Macrotin . . . ¼ gr. Phytolaccin . . . ⅛ gr. Colchicine . . . 1/300 gr. Caution: These capsules are to be used only by or on the prescription of a physician." After repackaging and relabeling it was labeled: "One Capsule Every hour for 4 doses Then One Every 4 hours Sam Frank Drug Co. Colfax at Downing—Denver Keystone 3217."

The article when repacked and relabeled was misbranded: (1) In that it contained colchicine, the frequent or continued use of which might result in abdominal pain (stomach ache, cramps, colic), nausea, vomiting, diarrhea, or bloody urine, and in that the statements on the label failed to bear adequate warnings against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users. (2) In that it was fabricated from two or more ingredients and its label did not bear the common or usual name of each active ingredient.

On March 16, 1942, the defendant entered a plea of guilty and the court imposed a fine of $10.

661. Misbranding of Nichol's Long Life For Health and Dickson's Laxative Diuretic. U. S. v. James B. Nichols (J. B. Nichols & Sons and Nichols Chemical Co.). Plea of guilty. Fine of $100 and jail sentence of 6 months. Sentences suspended and defendant placed on probation for 3 years. (F. D. C. No. 5475. Sample Nos. 39561–E, 39562–E.)

The labeling of the Laxative Diuretic failed to bear adequate warning statements; that of both products bore false and misleading therapeutic claims and inadequate ingredient and quantity of contents statements. The bottles containing both products were paneled in such manner as to be deceptive.

On January 26, 1942, the United States attorney for the Western District of Tennessee filed a libel against James B. Nichols, trading as J. B. Nichols & Sons, and as Nichols Chemical Co. at Memphis, Tenn., alleging shipment on or about November 12, 1940, from the State of Tennessee into the State of Arkansas of quantities of the above-named products that were misbranded.

Analyses of samples of the products showed that Nichol's Long Life for Health consisted of extracts of plant drugs, alcohol (13.0 percent by volume), and water; and that Dickson's Laxative Diuretic consisted essentially of Epsom salt, small proportions of caramel, methenamine, hysocyamine, salicyclic acid, sulfuric acid, and benzoic acid, minute amounts of strychnine and saccharin, and water.

Dickson's Laxative Diuretic was alleged to be misbranded: (1) In that its labeling did not bear adequate warnings against use in those pathological conditions where its use might be injurious to health or against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users, since its labeling did not bear a warning that it should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis are present, and that frequent or continued use might result in dependence on laxatives. (2) In that statements appearing on the bottle label which represented that each bottle contained 8 ounces of the drug, that it was efficacious as an aid in eliminating and correcting disorders of the alimentary canal and urinary organs, and that it would be efficacious in the treatment of biliousness, headache, gas on the stomach, and backache, were false and misleading since each bottle did not contain 8 ounces of the drug, but did contain a smaller amount, it was not efficacious as an aid in eliminating or correcting disorders of the alimentary canal or urinary organs and it would not be efficacious in the treatment of biliousness, gas on the stomach, or backache. (3) In that it was fabricated from two or more ingredients and its label did not bear the common or usual name of each active ingredient, including the quantity or proportion of hyoscyamine and strychnine, since (a) the declaration of "hyeciamus" was meaningless; (b) the label bore no statement of the quantity or proportion of strychnine; and (c) it failed to bear the common or usual name of methenamine since the designation "Utropian," appearing on the label, is not the common or usual name of methenamine. (4) In that it was in package form and the labeling failed to bear an accurate statement of the quantity of contents in terms of measure. (5) In that its container (bottle) was so made and formed as to be misleading.

Nichol's Long Life for Health was alleged to be misbranded: (1) In that statements on the bottle label representing that it would be efficacious to prolong

life; to maintain health, and that it would be efficacious for colds in the chest; nervousness, weakness, and all cold conditions of the system that cause consumption, were false and misleading since it would not be efficacious for such purposes. (2) In that it was fabricated from two or more ingredients and its label did not bear the common or usual name of each active ingredient including the quantity, kind, and proportion of alcohol that it contained. (3) In that it was in package form and did not bear a label containing the name and place of business of the manufacturer, packer, or distributor. (4) In that it was in package form and did not bear a label containing an accurate statement of the quantity of contents in terms of measure. (5) In that its container was so made, formed, or filled as to be misleading.

On February 10, 1942, a plea of guilty was entered on behalf of the defendant and the court imposed a fine of $100 and a jail sentence of 6 months. Payment of the fine and the jail sentence were suspended and the defendant was placed on probation for 3 years.

662. Misbranding of SMH Pur-Erb Compound No. 1 and "Helena" Pur-Erb Special No. 3. U. S. v. James M. Odell (Home Treatment Service). Plea of guilty. Fine, $25. (F. D. C. No. 5578. Sample Nos. 31963-E, 31964-E.)

The labels of both of these products failed to bear adequate directions for use and did contain false and misleading therapeutic claims; and the label for "Helena" Pur-Erb Special No. 3 failed to bear the required quantity of contents and ingredient statements. The label of the SMH Pur-Erb Compound also failed to bear adequate warning statements; it contained representations in certain foreign languages but failed to bear the required quantity of contents and ingredient statements in those foreign languages.

On February 27, 1942, the United States attorney for the Northern District of Illinois filed a libel against James M. Odell trading as Home Treatment Service at Chicago, Ill., alleging shipment on or about December 17, 1940, from the State of Illinois into the State of Indiana of quantities of the above-named products that were misbranded. The articles were labeled in part: "SMH Pur-Erb Compound No. 1 (Formerly Pur-Erb Tonic No. 1) * * * Prepared Only by Pur-Erb Products, Chicago, Ill." and "'Helena' Pur-Erb Special No. 3 * * * Kid-Ne Herb Compound * * * Herbal Health Products * * * Chicago."

Analyses of samples of the articles showed that SMH Pur-Erb Compound consisted essentially of extracts of plant drugs including laxative drugs such as aloes, senna, and cascara sagrada, and water; and that "Helena" Pur-Erb Special consisted essentially of extracts of plant drugs, solid plant material, and water.

SMH Pur-Erb Compound was alleged to be misbranded: (1) In that its label failed to bear adequate directions for use since those on the bottle label were indefinite as to amount. (2) In that the labeling failed to bear adequate warnings against unsafe methods or duration of administration in such manner and form as are necessary for the protection of users since it did not bear a warning that frequent or continued use might result in dependence on laxatives. (3) In that statements in the labeling representing and suggesting that it was efficacious in the treatment of chronic constipation; that it was a health prescription and would improve the general health; that it was an adequate remedy for constipation and colitis; and that it was efficacious in the treatment of serious, stubborn, obstinate or severe cases of constipation or colitis, were false and misleading since it would not be efficacious for such purposes. (4) In that certain information required by the act to appear on the label or labeling was not prominently placed thereon in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use since the label contained representations in foreign languages, namely, German, Polish, and Lithuanian, and by reason of said representations, it was labeled to appeal to persons understanding such foreign languages, and the label did not contain in said foreign languages an accurate statement of the quantity of the contents in terms of measure nor did said label bear in said foreign languages the common or usual name of each active ingredient.

"Helena" Pur-Erb Special was alleged to be misbranded: (1) In that the label failed to bear adequate directions for use since those given did not provide a limitation as to frequency and duration of its use. (2) In that the designation "Rx Kid-Ne Herb Compound" and the statements representing or suggesting that it was efficacious as a treatment of diseased conditions of the kidneys; that it was efficacious to overcome sluggish conditions of the genito-urinary system; that it was efficacious in the treatment of scant or excessive flow of urine; that it would be efficacious in the treatment of pains, aches, distresses and disturb-

ances of the water system; that it would alleviate the ills of humanity; and that it would be efficacious in the relief of many ailments, were false and misleading since it would not be efficacious for such purposes. (3) In that it was fabricated from two or more ingredients and its label failed to bear a statement of the common or usual name of each ingredient. (4) In that the label failed to bear an accurate statement of the quantity of contents in terms of measure.

On March 10, 1942, the defendant entered a plea of guilty and the court imposed a fine of $25.

663. Misbranding of Barkolyn. U. S. v. 9⅔ Dozen Packages of Barkolyn. Decree of condemnation and destruction. (F. D. C. No. 6586. Sample No. 54362–E.)

This product consisted essentially of extracts of plant drugs including laxatives, and strychnine; and the labeling failed to bear adequate directions for use, adequate warnings for the protection of users, and a statement of the qauntity or proportion of strychnine that it contained.

On December 24, 1941, the United States attorney for the Middle District of Pennsylvania filed a libel against 9⅔ dozen packages of Barkolyn at Lock Haven, Pa., alleging that the article had been shipped in interstate commerce on or about May 30, 1941, by Standard Medicines Co. from Columbus, Ohio; and charging that it was misbranded.

It was alleged to be misbranded: (1) In that the labeling failed to bear adequate directions for use since it was a laxative and the directions appearing on the labeling, which provided for continuous use, were inadequate since, if followed, they might lead to dependence on a laxative; and the directions for use by children were inadequate since they were indefinite. (2) In that the labeling failed to bear adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health, or against unsafe dosage or duration of administration, in such manner and form, as are necessary for the protection of users, since it failed to contain a warning that use of a preparation containing strychnine by children and elderly persons might be especially dangerous and since it also failed to contain a warning that a laxative should not be taken when suffering from nausea, vomiting, abdominal pains, or other symptoms of appendicitis, and that frequent or continued use might result in dependence on laxatives. (3) In that it contained strychnine and its label failed to bear a statement of the quantity or proportion of strychnine that it contained.

On January 31, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

664. Misbranding of Bosak's Horke Vino. U. S. v. 4½ Dozen Bottles of Bosak's Horke Vino. Default decree of condemnation and destruction. (F. D. C. No. 6395. Sample No. 74943–E.)

The labeling of this product failed to bear adequate directions for use and failed to bear a statement revealing the name and quantity of strychnine present in the article and also bore false and misleading therapeutic claims.

On December 17, 1941, the United States attorney for the Southern District of New York filed a libel against 4½ dozen bottles of Bosak's Horke Vino at New York, N. Y., alleging that the article had been shipped in interstate commerce on or about September 4 and December 3, 1941, by Gold Seal Manufacturing Company from Scranton, Pa.; and charging that it was misbranded.

Analysis of a sample of the article showed that it consisted essentially of small proportions of aloin and strychnine, alcohol, and water.

The article was alleged to be misbranded: (1) In that its labeling did not bear adequate directions for use since it was a laxative preparation and the directions for use were inadequate for a laxative preparation, and in that the directions failed to place a limitation on the period of time for taking the recommended daily dosage. (2) In that the following statements appearing in the labeling, "Nature's Tonic * * * This Tonic has been found a valuable aid in cases of Indigestion, Dyspepsia * * * Nervousness, General Debility, and in other derangements of the digestive organs," and also "These goods are labeled to conform to requirements of New Federal Food, Drug, and Cosmetic Law, which is effective June 25th, 1939," were false and misleading since it was not a tonic, it did not possess natural tonic properties bestowed by nature, it was not a valuable aid in the case of indigestion, dyspepsia, nervousness, general debility, and any other derangements of the digestive organs, and it was not labeled to conform to the requirements of the law. (3) In that strychnine was

one of its ingredients and its label failed to bear the name and quantity of such ingredient.

On January 14, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

665. Misbranding of Grover Graham Remedy. U. S. v. 37 Bottles and 71 Bottles of Grover Graham Remedy. Default decree of condemnation and destruction. (F. D. C. No. 6213. Sample No. 74151–E.)

The labeling of this product in addition to failure to bear adequate directions and warning statements, contained false and misleading therapeutic claims.

On November 14, 1941, the United States attorney for the District of New Jersey filed a libel against 37 6-fluid-ounce bottles and 71 12-fluid-ounce bottles of Grover Graham Remedy at Jersey City, N. J., alleging that the article had been shipped on or about January 20 and July 15, 1941, by S. Grover Graham Co., Inc., from Newburgh, N. Y.; and charging that it was misbranded.

Analyses of samples of the article showed that it consisted essentially of magnesia, sodium bicarbonate, sodium bromide, extract of ginger, a small proportion of chloroform, alcohol, and water flavored with peppermint oil and colored with a violet red dye. Analysis of a sample of Graham's Pills showed that they contained aloe, podophyllin, gamboge, and capsicum.

The article was alleged to be misbranded: (1) In that the labeling did not bear adequate directions for use since those given provided for an excessive amount of sodium bromide, and no limitation was put on the amount of bromide to be administered daily. (2) In that the labeling failed to bear adequate warnings against use in those pathological conditions where its use might be dangerous to health, or against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users, since it did not bear any warning that frequent or continued use might lead to mental derangement, skin eruptions, or other serious effects; and that it should not be taken by those suffering from kidney diseases. (3) In that statements in the labeling representing that it would be efficacious for treatment of indigestion, bloating, dyspepsia, gastritis, constipation, and other forms of stomach disorders and distress due to faulty digestion; and that it was harmless, not habit-forming, and could be taken with perfect safety, were false and misleading since it would not be efficacious for the purposes recommended, it was not harmless, it was habit-forming and could not be taken with perfect safety since it contained a material proportion of sodium bromide, a habit-forming drug. (4) In that the following statement regarding another drug (cartons) "For temporary relief from occasional constipation we recommend Graham's Pills, and intestinal eliminant specially prepared for use with this remedy," was false and misleading since it represented that Graham's Pills, when used in conjunction with Grover Graham's Remedy, would be efficacious for the purposes for which the latter article was recommended.

On January 8, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

666. Misbranding of Herb Doctor Compound. U. S. v. 56 Bottles of Herb Doctor Compound. Default decree of condemnation and destruction. (F. D. C. No. 6359. Sample No. 54335–E.)

On December 5, 1941, the United States attorney for the Eastern District of Pennsylvania filed a libel against 56 bottles of Herb Doctor Compound at Lancaster, Pa., alleging that the article had been shipped on or about September 25, 1941, by Strong Cobb & Co. from Cleveland, Ohio; and charging that it was misbranded in that its labeling failed to bear adequate directions for use, since those given provided for its use under conditions which might have rendered it injurious to the user by creating a dependence upon laxatives to move the bowels.

On January 5, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

667. Misbranding of laxative cold tablets. U. S. v. 172 Tins of Norwich Laxative Cold Tablets. Default decree of condemnation and destruction. (F. D. C. No. 6719. Sample No. 90408–E.)

The labeling of this product in addition to failure to bear adequate warning statements, also contained false and misleading therapeutic claims.

On January 16, 1942, the United States attorney for the District of Rhode Island filed a libel against the above-named product at Newport, R. I., alleging

that it had been shipped on or about November 7, 1941, by the Norwich Pharmacal Co. from Norwich, N. Y.; and charging that it was misbranded.

Analysis of a sample of the article showed that the tablets each contained acetanilid (1 grain), a coal-tar analgesic drug, podophyllin, aloin, and other drugs of plant origin including quinine, camphor, and cayenne pepper.

The article was alleged to be misbranded: (1) In that the labeling did not bear such adequate warnings against unsafe duration of administration as are necessary for the protection of users, since it failed to warn the consumer that frequent or continued use might be dangerous, causing serious blood disturbances, anemia, collapse, or dependence on the drug, and that it should be discontinued if skin rash appears. (2) In that statements in the labeling representing that it would affect the underlying cause of the common cold, prevent its full development, and shorten its duration were false and misleading, since its therapeutic efficacy was limited to that of an analgesic and laxative which might temporarily ameliorate some of the symptoms of the common cold, but not those of feverishness, tickling throat sensations, and running of the nose.

On April 1, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

668. Adulteration and misbranding of Pinee. U. S. v. 90 Bottles of Pinee. Default decree of condemnation and destruction. (F. D. C. No. 6549. Sample No. 59472–E.)

In addition to containing smaller proportions of acetanilid and alcohol than those stated on the label, this product failed to bear on its label adequate directions for use and warning statements. The label also contained false and misleading therapeutic claims; and the statements of the active ingredients and quantity of contents and directions for use were in type so small as to be illegible.

On December 19, 1941, the United States attorney for the Eastern District of Virginia filed a libel against the above-named product at Emporia, Va., alleging that it had been shipped on or about October 1, 1941, by the Pinee Chemical Co. from Kinston, N. C.; and charging that it was adulterated and misbranded.

Analysis of a sample of the article showed that it consisted essentially of acetanilid (not more than 3.6 grains per fluid ounce), alcohol (not more than 10.9 percent), small amounts of menthol, camphor, laxative plant drugs, ammonia, ammonium chloride, licorice, and a trace of alkaloids.

The article was alleged to be adulterated in that its strength differed from that which it was represented to possess, namely, "Acetanlid 6 grs to oz Maximum Alcohol 20 per cent."

It was alleged to be misbranded: (1) In that the labeling did not bear adequate directions for use since those appearing on the label provided for continuous administration and such directions were inadequate for a laxative since when taken in such manner it might create a dependence on laxatives (2) In that the labeling did not bear adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health, or against unsafe dosage or duration of administration in such manner and form as are necessary for the protection of users since the labeling failed to warn that frequent or continued use might result in dependence on laxatives. (3) In that the following statements appearing in the labeling, together with the design of pine trees and pine cones on the bottle label, (carton) "Pinee For Colds," and (bottle label) "Pinee Colds * * * Very effective In Treatment of Head & Chest Colds * * * Contents Acetanlid 6 Grs to oz Maximum Alcohol 20 per cent," were false and misleading since the article contained no ingredient or combination of ingredients capable of preventing or curing either head or chest colds or of alleviating the common symptoms characteristic of colds, and it contained no materials derived from pine trees or pine cones, as implied by the designs on the label. (4) In that the required statements of the active ingredients, of the quantity of contents, and the directions for use did not appear on the label with such prominence or conspicuousness as to render them likely to be read or understood by the ordinary individual under customary conditions of purchase and use, since they appeared in type so small as to be illegible.

On February 18, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

669. Misbranding of Special Formula Tablets. U. S. v. 47,800 Special Formula Tablets, Plain. Default decree of condemnation and destruction. (F. D. C. No. 6301. Sample Nos. 87220–E, 87221–E.)

This product consisted of tablets containing boric acid and an effervescent mixture of soda and citric acid. Its use might produce deleterious effects and its

label failed to bear adequate directions for use, adequate warnings, and the names of the active ingredients.

On November 28, 1941, the United States attorney for the Southern District of West Virginia filed a libel against the above-named product at Charleston, W. Va., alleging that the article had been shipped in interstate commerce on or about October 15, 1941, by the Arner Co., Inc., from Buffalo, N. Y.; and charging that it was misbranded.

The article was alleged to be misbranded in that its label failed to bear (1) adequate directions for use; (2) adequate warnings against use by children where its use might be dangerous to health, and against unsafe dosage or duration of administration, in such manner and form as are necessary for the protection of users, since the labeling carried no warning that repeated daily administration would cause systemic deleterious effects and injurious gastro-intestinal disturbances; and (3) the common or usual name of each active ingredient.

On April 20, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

670. Misbranding of Special S. C. White Pills Rx2609. U. S. v. 96,200 Special S. C. White Pills Rx2609. Default decree of condemnation and destruction. (F. D. C. No. 6744. Sample No. 30492-E.)

On January 21, 1942, the United States attorney for the Eastern District of Michigan filed a libel against the above-named product at Detroit, Mich., alleging that it had been shipped on or about November 22, 1941, by Charles H. Dietz, Inc., from St. Louis, Mo.; and charging that it was misbranded. The article was labeled in part: "Special S. C. White Pills Rx2609. Each pill contains—Aloes—¾ gr. Ferrous Sulphate—1¼ gr. Oil Pennyroyal—¼ min."

It was alleged to be misbranded (1) in that the label did not bear adequate directions for use; and (2) in that the labeling failed to bear adequate warnings against use in those pathological conditions where its use might be dangerous to health since the label failed to bear a warning that it should not be taken when nausea, vomiting, abdominal pains, or other symptoms of appendicitis are present; and against unsafe dosage or duration of administration since the labeling failed to bear a warning that frequent or continued use might result in dependence on a laxative.

On March 24, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

671. Misbranding of Sterile Solution Formula No. 3, Rx Formula No. 8, and S. G. M. a. (Oral). U. S. v. 8 Vials of Sterile Solution Formula No. 3, 12 Boxes of Rx Formula No. 8, and 4 Bottles of S. G. M. a. (Oral). Default decree of condemnation and destruction. (F. D. C. No. 3911. Sample Nos. 50191-E, 50195-E, 50196-E.)

The labeling of the Sterile Solution Formula No. 3 and S. G. M. a (Oral) failed to bear adequate directions for use and such adequate warnings as are necessary for the protection of users and failed to bear the common or usual names of the active ingredients including the amount of strychnine in the former and of thyroid in the latter. The labeling of all three products failed to comply with certain other labeling requirements, as indicated hereinafter.

On February 4, 1941, the United States attorney for the Eastern District of Virginia filed a libel against the above-named products at Richmond, Va., alleging that they had been shipped in interstate commerce on or about December 31, 1940, by The Samaritan Treatment from Chicago, Ill.; and charging that they were misbranded.

Analysis of a sample of the Sterile Solution Formula No. 3 showed that it contained a solution of strychnine, emetine, ephedrine, pilocarpine, and sparteine. It was alleged to be misbranded (1) in that the label failed to bear adequate directions for use; (2) in that the label failed to bear adequate warnings against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users; and (3) in that the label failed to bear the common or usual name of each of the active ingredients, including the amount of strychnine that it contained.

Analysis of a sample of Rx Formula No. 8 showed that the capsules each contained approximately 0.6 gram of a powder composed chiefly of iron and ammonium citrate. They were alleged to be misbranded in that they did not bear a label containing the name and place of business of the manufacturer, packer, or distributor; in that they did not bear a label containing a statement of the quantity of contents of the package; in that the label failed to bear the common

or usual name of the drug; and in that the label failed to bear the common or usual name of each active ingredient contained therein.

Analysis of a sample of the S. G. M. a (Oral) showed that it consisted of capsules containing animal materials including 0.16 grain of thyroid per capsule. It was alleged to be misbranded in that its labeling failed to bear adequate directions for use; in that its labeling failed to bear adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health or against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users; in that its package failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; in that its package failed to bear a label containing a statement of the quantity of the contents; in that the label failed to bear the common or usual name of the article; and in that the label failed to bear the common or usual name of each active ingredient, including the quantity of thyroid that it contained.

On January 7, 1942, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

672. Adulteration and misbranding of Zerbst's Capsules. U. S. v. 94 Dozen Packages of Zerbst's Capsules. Default decree of destruction. (F. D. C. No. 6572. Sample No. 73122–E.)

This product contained acetanilid, aloin, and a resin such as podophyllin. In addition to failure to bear adequate directions and warnings on the label, it contained approximately 20 percent more acetanilid than the amount stated on the label.

On December 24, 1941, the United States attorney for the Western District of Missouri filed a libel against 94 dozen packages of Zerbst's Capsules at Kansas City, Mo., alleging that the article had been shipped on or about November 15, 1941, by J. Walker Burns & Co. from Chicago, Ill.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that its strength differed from that which it purported or was represented to possess, namely, (label) "Each Capsule contains as active ingredients, Acetanilid 1 Grain," since it contained materially more than 1 grain of acetanilid.

It was alleged to be misbranded: (1) In that the directions for use, "Adults—To allay the discomfort in breaking up a common head cold, simple headache or neuralgia, take one capsule every half hour until three are taken, then one capsule in two or three hours until three more capsules are taken. Children—12 years old, one capsule, repeated in three hours," were inappropriate for an article of its composition and were therefore inadequate. (2) In that the label failed to bear adequate warnings against its use by children or in those pathological conditions where its use might be dangerous to health and against unsafe dosage or duration of administration, in such manner and form as are necessary for the protection of users, since there was no warning against its use by children, against use in the presence of the symptoms of appendicitis, nor with reference to the deleterious effects of acetanilid in causing serious blood disturbances, or that frequent or continued use might result in dependence upon the drug.

On February 13, 1942, no claimant having appeared, judgment was entered ordering that the product be destroyed.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO COMPLY WITH OFFICIAL OR OWN STANDARDS[2]

673. Adulteration of chloroform. U. S. v. City Chemical Corporation and Max Wolpert. Plea of guilty. Corporation and Max Wolpert both fined $100. (F. D. C. No. 6404. Sample Nos. 47480–E, 50848–E.)

This product differed from the pharmacopoeial standard because of the presence of excessive carbonizable substances in both lots and of chlorinated decomposition products in one.

On February 18, 1942, the United States attorney for the District of New Jersey filed an information against the City Chemical Corporation, Newark, N J., and Max Wolpert, an officer of said corporation, alleging shipment on or about May 27, 1941, from the State of New Jersey into the States of Illinois and Maryland, of a quantity of chloroform that was adulterated.

The article was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, but its quality or purity fell below the standard set forth in

[2] See also Nos. 656, 657, 668, and 672.

such compendium since it contained carbonizable substances in excess of the maximum provided by the pharmacopoeia, and (in one lot) chlorinated decomposition products and its difference in quality or purity from said standard was not plainly stated on the label.

On February 24, 1942, a plea of guilty having been entered on behalf of the defendants, the court imposed a fine of $50 against the corporation and the individual defendant on each of the two counts.

674. Adulteration and misbranding of magnesium carbonate. U. S. v. City Cemical Corporation and Max Wolpert. Plea of guilty. Corporation and Max Wolpert each fined $100. (F. D. C. No. 2973. Sample No. 99913-E.)

This product was labeled as magnesium carbonate, but consisted of approximately 96 percent of calcium carbonate.

On November 7, 1941, the United States attorney for the District of New Jersey filed an information against the City Chemical Corporation, Jersey City, N. J., and Max Wolpert, an officer of said corporation, alleging shipment on or about November 12, 1940, from the State of New Jersey into the District of Columbia, of a quantity of magnesium carbonate that was adulterated and misbranded.

The article was alleged to be adulterated (1) in that a product consisting of approximately 96 percent of calcium carbonate had been substituted in whole or in part for magnesium carbonate; and (2) in that it purported to be or was represented as a drug the name of which is recognized in the United States Pharmacopoeia, but its strength differed from or its quality or purity fell below the standard set forth in the pharmacopoeia and its difference in strength, quality, or purity from such standard was not plainly stated on the label.

It was alleged to be misbranded (1) in that the statement on the label, "Magnesium Carbonate * * * U. S. P.," was false and misleading; and (2) in that it consisted essentially of calcium carbonate and was offered for sale under the name of another drug. "Magnesium Carbonate U. S. P."

On February 24, 1942, a plea of guilty having been entered on behalf of the defendants, the court imposed a fine of $50 on count 1 and $25 each on counts 2 and 3 against both the corporation and the individual defendant.

675. Adulteration and misbranding of oxygen and carbon dioxide mixture. U. S. v. Stuart Oxygen Co. Plea of nolo contendere. Fine, $200. (F. D. C. No. 5536. Sample No. 55252-E.)

This product was represented to contain 7 percent of carbon dioxide, whereas it contained 9 percent of carbon dioxide.

On December 22, 1941, the United States attorney for the Northern District of California filed an information against Stuart Oxygen Co., a corporation, San Francisco, Calif., alleging shipment on or about September 21, 1940, from the State of California into the State of Washington of a quantity of oxygen and carbon dioxide mixture which was adulterated and misbranded. It was labeled in part: "Stuart Medical Oxygen-Carbon Dioxide Mixture * * * 93% Oxygen—7% Carbon Dioxide."

The article was alleged to be adulterated in that its strength differed from that which it purported and was represented to possess since it was represented to contain not more than 7 percent of carbon dioxide, but did contain not less than 9 percent of carbon dioxide.

It was alleged to be misbranded in that the statements, (cylinders) "Carbon Dioxide, not more than 7%," (wrappers) "7% Carbon Dioxide," and (tags) "CO_2 * * * 7% Carbon Dioxide," were false and misleading.

On January 2, 1942, the defendant entered a plea of nolo contendere and the court imposed a fine of $200.

676. Adulteration and misbranding of Camphor Liniment, Anthelmintic Tablets, and Kamala Compound No. 1 Tablets; and misbranding of Marnecro Concentrate, Maresby Tablets, and Fowl Enteric Tablets. U. S. v. Marrinan Supply Co., Inc. Plea of guilty. Fine, $45. (F. D. C. Nos. 4137, 5480. Sample Nos. 38116-E, 38404-E, 38647-E, 38659-E, 38660-E, 38661-E.)

The Camphor Liniment differed from the pharmacopoeial requirements. The Anthelmintic Tablets and Kamala Compound No. 1 fell below their declared standards and they and the remaining products bore on their labeling false and misleading claims regarding their efficacy in the treatment of diseases of animals and poultry. The Marnecro Concentrate was falsely represented to contain copper arsenite and its label failed to bear an accurate statement of the quantity of the contents.

On October 27, 1941, the United States attorney for the District of Minnesota filed an information against the Marrinan Supply Co., Inc., St. Paul, Minn., al-

leging shipment within the period from on or about September 9 to on or about October 18, 1940, from the State of Minnesota into the States of Wisconsin, Iowa, North Dakota, and South Dakota of quantities of the above-named products which were misbranded and portions of which were also adulterated.

The Camphor Liniment was alleged to be adulterated: (1) In that it purported to be or was represented as a drug the name of which is recognized in the United States Pharmacopoeia but its strength differed from or its quality or purity fell below the standard set forth in such compendium since it contained not more than 1.7 percent of camphor, and did contain small proportions of ammonium chloride, ammonia water, and aromatics, whereas the pharmacopoeia provides that camphor liniment shall contain not less than 19 percent of camphor, and does not mention ammonium chloride, ammonia water, or aromatics as constituents of camphor liniment; and the difference in strength, quality, or purity from such standard was not plainly stated on the label. (2) In that a substance containing not more than 1.7 percent of camphor, small proportions of ammonium chloride, ammonia water, and aromatics had been substituted wholly or in part for camphor liniment, which it purported to be. It was alleged to be misbranded in that the statement "Camphor Liniment," appearing on the label, was false and misleading.

Analysis of the Marnecro Concentrate showed that it consisted essentially of charcoal, sulfur, copper sulfate, sodium sulfate, iron sulfate, and sodium chloride, but no copper arsenite or other arsenic-bearing substances. It was alleged to be misbranded (1) in that representations in the labeling that it was efficacious in the prevention and cure of necrotic enteritis in pigs; and as an antiseptic, vermifuge, and febrifuge; that it would absorb and hold deleterious gases, increase gastric juices, aid digestion, eliminate waste from the body, and purify the blood; and would be efficacious in the treatment of scours, were false and misleading since it would not be efficacious for such purposes; (2) in that the statement "Copper Arsenite" on the label was false and misleading since it contained no copper arsenite; and (3) in that it was in package form and its label did not bear an accurate statement of the quantity of the contents in terms of weight.

Analysis of the Anthelmintic Tablets showed that they contained not more than 5.23 grains of kamala and not more than 8.62 grains of copper sulfate per tablet. They were alleged to be adulterated in that their strength differed from or their quality or purity fell below that which they purported and were represented to possess, since each of the tablets purported and was represented to contain 10 grains of kamala and 10 grains of copper sulfate; whereas the tablets each contained not more than 5.23 grains of kamala and not more than 8.62 grains of copper sulfate. They were alleged to be misbranded (1) in that statements in the labeling which represented that they were efficacious as an anthelmintic, for the control of "tapeworm infection," to remove stomach worms, and as a general anthelmintic agent for sheep and goats, were false and misleading since they were not efficacious for such purposes; and (2) in that the statement "Each Tablet Contains: Kamala 10 grs. Copper Sulphate 10 grs.," borne on the box, was false and misleading since the tablets contained less kamala and copper sulfate than the amounts represented.

Analysis of the Maresby Tablets showed that they consisted essentially of eucalyptol, small proportions of guaiacol, potassium chlorate, and a chromium compound, with inert ingredients such as calcium carbonate and magnesium carbonate. They were alleged to be misbranded in that the statement "Roup" appearing on the boxes was false and misleading since they were not efficacious in the treatment of roup in poultry.

Analysis showed that the Kamala Compound No. 1 Tablets contained not more than 7.12 grains of kamala and not less than 1.20 grains of nicotine sulfate per tablet. They also contained calomel, a mercurial derivative, in the amount of approximately ½ grain per tablet. They were alleged to be adulterated in that their strength differed from that which they purported and were represented to possess since each of the tablets was represented to contain 9 grains of kamala and ¼ grain of nicotine sulfate; whereas the tablets contained not more than 7.12 grains of kamala and not less than 1.20 grains of nicotine sulfate. They were alleged to be misbranded (1) in that the statement in the labeling which represented that they were efficacious for the treatment of poultry infested with roundworms or tapeworms was false and misleading since they would not be efficacious for such purposes; (2) in that the statement "Tablets * * * Kamala 9 grs. Nicotine Sulphate ¼ gr.," appearing on the boxes, was

false and misleading since the tablets contained not more than 7.12 grains of kamala and not less than 1.20 grains of nicotine sulfate; and (3) in that they were fabricated from two or more ingredients and contained the ingredient calomel, a derivative or preparation of mercury, and the label did not show that said ingredient was a derivative or preparation of mercury.

Analysis showed that the Fowl Enteric Tablets consisted essentially of compounds of calcium, sodium, and copper, sulfates, phenolsulfates, and approximately 1/10 grain of copper arsenite per tablet.

They were alleged to be misbranded (1) in that the statements in the labeling which represented that they were efficacious in the treatment of enteritis, blackhead, and various intestinal infections in fowls were false and misleading since they were not efficacious for such purposes; and (2) in that they were fabricated from two or more ingredients and contained arsenic, but the label did not bear the common or usual name of each active ingredient, including the quantity or proportion of arsenic that they contained.

On November 12, 1941, a plea of guilty was entered on behalf of the defendant and a fine of $45 was imposed by the court.

677. Adulteration and misbranding of Cal-Par. U. S. v. 26 Dozen Packages and 6 Dozen Packages of Cal-Par with circulars entitled "Dr. Parrish's 7 Day Reducing Plan" and display cards entitled "Lose Fat." Default decree of condemnation and destruction. (F. D. C. No. 5237. Sample No. 61018–E.)

This product, in addition to being more than 50 percent deficient in phosphorus, contained in its labeling false and misleading claims regarding its value as a weight reducer and as a treatment for various diseases and disease conditions.

On or about August 12, 1941, the United States attorney for the Western District of Washington filed a libel against 26 dozen 7-ounce packages and 6 dozen 16-ounce packages of Cal-Par, together with all circulars entitled "Dr. Parrish's 7 Day Reducing Plan" and all display cards entitled "Lose Fat" at Seattle, Wash., alleging that the article had been shipped by Hood Products Corporation from New York, N. Y., on May 10 and 14, 1941; and charging that it was adulterated and misbranded.

Microscopic examination of a sample of the article showed that it contained wheat germ, wheat bran, crystalline material, and wheat flour Chemical examination showed that it contained calcium, phosphorus, and iron salts, and sugar.

The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it was represented to possess, namely, 1.8 grams of phosphorus per 2 heaping teaspoonfuls; whereas it contained much less than 1.8 grams of phosphorus per 2 heaping teaspoonfuls.

The article was alleged to be misbranded in that representations in the labeling that it would supply the average person's daily needs of phosphorus; that it would build strong teeth, sturdy bones, firm flesh, pliant muscles, and efficient brain cells; that it was an aid for underweight and for reducing overweight; that it would protect the user against nervousness, tiredness, sleeplessness, and lack of pep and vigor; that it would prevent heart trouble, nervous disorders, kidney complaints, liver ailments, digestive upsets, eye afflictions, and many other ailments due to the lack of certain vitamins and minerals; that it would aid in maintaining the acid-base equilibrium of the blood; that it would furnish nourishment to nerves and the brain; that it constituted an adequate treatment in anemia conditions, run-down conditions, and sinus trouble; and would relieve the pains of arthritis and rheumatism, were false and misleading since it would not be efficacious for such purposes.

It also was alleged to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in F. N. J. No. 3648.

On December 30, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

678. Adulteration of tincture of digitalis. U. S. v. 5 Bottles of Tincture Digitalis. Default decree of condemnation and destruction. (F. D. C. No. 3871. Sample No. 37766–E.)

The potency of this article exceeded by approximately 50 percent the maximum potency for tincture of digitalis as specified in the United States Pharmacopoeia.

On February 27, 1941, the United States attorney for the Northern District of Georgia filed a libel against 5 bottles of tincture of digitalis at Atlanta, Ga., alleging that the article had been shipped in interstate commerce on or about December 9, 1940, by the Standard Pharmaceutical Corporation from Baltimore, Md.; and charging that it was adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States

Pharmacopoeia, an official compendium, but its strength differed from the standard set forth in such compendium. It was labeled in part: "Tincture Digitalis U. S. P."

On January 5, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

679. Adulteration and misbranding of Individual Quinine Hair Treatment; misbranding of Daigneault's Eau de Quinine Hair Tonic. U. S. v. 66 Bottles of Daigneault's Eau de Quinine Hair Tonic and 488 Packages of Individual Quinine Hair Treatment. Default decree of condemnation and destruction. (F. D. C. Nos. 2644, 2645. Sample Nos. 24241–E, 24242–E.)

The labeling of these products bore false and misleading representations regarding their efficacy in the treatment of the conditions indicated hereinafter, and also failed to comply with certain mandatory labeling requirements of the law. The hair tonic contained less alcohol than the amount declared, and the hair treatment was not antiseptic as claimed in the labeling.

On August 21, 1940, the United States attorney for the Eastern District of Pennsylvania filed a libel against the above-named products at Philadelphia, Pa., which had been consigned by Joseph Daigneault, alleging that the articles had been shipped in interstate commerce on or about June 3, 1940, from Malone, N. Y.; and charging that they were misbranded and that the hair treatment was also adulterated.

Analysis of the hair tonic showed that it consisted essentially of alcohol (59 percent), water, a small proportion of quinine, perfume, and coloring matter. Examination of the hair treatment showed that each package contained tubes labeled No. 1 and No. 2. The product in tube No. 1 consisted essentially of mineral oil, a small proportion of a fatty oil, and carbolic acid; and that in tube No. 2 consisted essentially of soap and water. Bacteriological tests showed that the hair treatment was not antiseptic.

The hair treatment was alleged to be adulterated in that its strength differed from and its purity or quality fell below that which it purported or was represented to possess, namely, "antiseptic." It was alleged to be misbranded (1) in that the statements "Antiseptic * * * Quinine Hair Treatment Joseph Daigneault New York Chicago * * * Removing Dandruff in one application. Promotes growth of the Hair in the worst cases and in which other treatments have failed. * * * puts it in a permanently healthy condition," represented that it was efficacious for the purposes recommended, whereas it was not efficacious for such purposes; (2) in that the label did not bear an accurate statement of the quantity of contents; and (3) in that it did not bear the common or usual names of the active ingredients.

The hair tonic was alleged to be misbranded (1) in that the following statements in the labeling, "Compounded with 68% Alcohol * * * prevents falling out and promotes growth of the Hair," were false and misleading, since it would not be efficacious for the purposes recommended; and (2) in that the label did not bear an accurate statement of the quantity of the contents. Both products were alleged to be misbranded further in that the labels did not bear the name and address of the manufacturer, packer, or distributor, since the address of the manufacturer borne on the labels was incorrect.

On February 16, 1942, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

680. Adulteration and misbranding of Bevimin. U. S. v. 43 Vials of Bevimin Vitamin B_1 Hydrochloride. Decree of condemnation and destruction. (F. D. C. No. 2365. Sample No. 1977–E.)

This product was labeled as containing 10 milligrams of vitamin B_1 per cubic centimeter, whereas it contained not more than 7 milligrams of vitamin B_1 per cubic centimeter.

On July 15, 1940, the United States attorney for the Eastern District of Virginia filed a libel against 43 vials of the above-named product at Richmond, Va., alleging that it had been shipped in interstate commerce on or about June 29, 1939, by the Loeser Laboratory, Inc., from New York, N. Y.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it was represented to possess, namely, (label) "Each c.c.=10 MG.=3000 I.U." and (carton) "Each cc. contains 10 Mg. (3,000 I.U.)," since it did not contain 10 milligrams of vitamin B_1 per cubic centimeter, but did contain a smaller amount. It was alleged to be misbranded

in that the statements on the label and carton quoted hereinbefore were false and misleading since they were incorrect.

On January 7, 1942, the sole intervenor having withdrawn its appearance, judgment of condemnation was entered and the product was ordered destroyed.

681. Adulteration and misbranding of Coreco Vitamins A–B,–G–D Capsules. U. S. v. 512 Boxes of Coreco Vitamins A–B,–G–D Capsules. Default decree of condemnation and destruction. (F. D. C. No. 6777. Sample No. 23110–E.)

Each of these capsules was represented to contain 50 International Units of vitamin B_1 and 1,000 U. S. P. units of vitamin D; whereas examination showed that they contained less than 12.5 International Units of vitamin B_1 and not more than 850 U. S. P. units of vitamin D.

On January 29, 1942, the United States attorney for the Northern District of California filed a libel against the above-named product at San Francisco, Calif., alleging that it had been shipped in interstate commerce on or about May 25, 1940, by the International Vitamin Corporation from New York, N. Y.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it was represented to possess, namely, 50 International Units of vitamin B_1 and 1,000 U. S. P. units of vitamin D per capsule, since it contained smaller amounts of both vitamins.

It was alleged to be misbranded in that the following statements were false and misleading since when taken in the dosage of 1 capsule per day as directed, it would not furnish "moderate amounts" of vitamins B_1 and G: "Biologically Assayed and Standardized * * * each capsule contains not less than: * * * 1,000 U. S. P. Units of Vitamin D, 50 International Units of Vitamin B_1 (approx. 100 Chase-Sherman Units) * * * Each capsule is equivalent in U. S. P. Units of Vitamins * * * D to not less than 3 teaspoonfuls of Cod Liver Oil U. S. P., assaying * * * 85 Vitamin D Units per gram. Each capsule furnishes * * * moderate amounts of Vitamin B_1 and G to supplement the supply of these vitamins contained in the diet."

It also was alleged to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in F. N. J. No. 3425.

On March 9, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING STATEMENTS IN THE LABELING [3]

682. Misbranding of Castoria and Crompton's Liniment. U. S. v. Charles Crompton & Sons, Inc., and George Crompton. Pleas of guilty. Fines, $20. (F. D. C. No. 5539. Sample Nos. 36263–E, 36861–E.)

The labeling of these products bore false and misleading curative and therapeutic claims, and the labeling of Crompton's Liniment failed to bear the common or usual names of the active ingredients.

On January 19, 1942, the United States attorney for the District of Massachusetts filed an information against Charles Crompton & Sons, Inc., Lynn, Mass., and George Crompton, alleging shipment on or about December 4 and 5, 1940, from the State of Massachusetts into the State of Vermont of quantities of Castoria and Crompton's Liniment which were misbranded.

Analyses of samples of the articles showed that the Castoria consisted of sugar, alcohol, water, methyl salicylate, oil of anise, Rochelle salt, and plant extractives including senna; and that Crompton's Liniment consisted of a fatty oil and volatile oils including camphor, methyl salicylate, and probably eucalyptol.

The Castoria was alleged to be misbranded in that representations in the labeling that it was a remedy for regulating stomach and bowels; was especially useful in convulsions, colic, feverishness, diarrhea, sour stomach, loss of sleep, and worms; and that it would aid digestion and promote rest, were false and misleading since it would not be efficacious for such purposes.

Crompton's Liniment was alleged to be misbranded in that representations in the labeling that it would be efficacious in the treatment of rheumatic pains, numbness of the limbs, contraction of the muscles, pains in the side, chest, and back, hoarseness, sore throat, quinsy, and common and severe cases of headache, were false and misleading since it would not be efficacious for such purposes. It was alleged to be misbranded further in that it was fabricated from two or more

[3] See also Nos. 657–659, 661, 662, 664, 665, 667, and 668.

ingredients, and its label did not bear the common or usual name of each active ingredient.

On February 21, 1942, pleas of guilty were entered and the court imposed a fine of $10 on each of the defendants.

683. Misbranding of Life Line Tonic. U. S. v. John B. Kori (United States Remedy Co.). Plea of nolo contendere. Fine of $100, and sentence of 6 months' imprisonment. Sentence suspended and defendant placed on probation for 1 year. (F. D. C. No. 5474. Sample No. 40426–E.)

The labeling of this product bore false and misleading claims regarding its therapeutic efficacy and its ingredients. It also failed to declare the kind and proportion of alcohol that it contained.

On September 15, 1941, the United States attorney for the Southern District of Florida filed an information against John B. Kori, trading as United States Remedy Co., Jacksonville, Fla., alleging shipment on or about October 17, 1940, from the State of Florida into the State of Pennsylvania of a quantity of Life Line Tonic which was misbranded.

Analysis showed that the article consisted of a water-glycerin solution containing large amounts of Epsom salt, smaller amounts of sodium sulfate and sodium phosphate and small amounts of quinine, iron, caffeine, saccharin and plant extractives including emodin.

The article was alleged to be misbranded: (1) "In that statements in the labeling which represented that it would be efficacious in the treatment of sour stomach, biliousness, colic, cramps due to gas, and temporary listlessness; that it would be beneficial in malarial and feverish conditions due to chills and colds; would check chills and malarial fever; would build resistance; would be efficacious in the treatment of colds, stuffiness of nasal passages, simple headache, neuralgia, and malarial fever; that it would be efficacious to keep the system clean and invigorated; and would be efficacious in the treatment of simple headache due to occasional constipation and neuralgia; that the distress and misery of common colds would generally be relieved within a few hours by it; that it would not be habit-forming; that it was a tonic and possessed value as a treatment in emergencies, as suggested by the name "Life-Line," were false and misleading since it would not be efficacious for such purposes, and might be habit-forming, i. e., might form the laxative habit. (2) In that it was fabricated from two or more ingredients and its label did not bear the common or usual name of each active ingredient, including the quantity, kind, and proportion of alcohol that it contained, since the common or usual name of each active ingredient and the quantity, kind, and proportion of alcohol did not appear on the outside container, namely, the carton. (3) In that the statement, "Active Ingredients—Ext. of Leaves and Flowering tops of Eupatorium Perfoliatum (Boneset), Extract Sacred tree bark (Rhamnus Purshiana) Sodium Phosphate, Sodium Sulphate, Iron & Ammonium Citrate, May Apple (Mandrake), Magnesium Sulphate (Epsom Salts), Citrated Caffein, Citric Acid, Quinine Sulphate, other ingredients," represented and suggested that it contained each of said ingredients and substances in amounts sufficient to be of therapeutic importance; whereas it did not contain boneset, iron and ammonium citrate, and citric acid in amounts which were therapeutically important.

On January 5, 1942, the defendant having entered a plea of nolo contendere, the court imposed a fine of $100 and a sentence of 6 months' imprisonment. The jail sentence was suspended and the defendant was placed on probation for 1 year.

684. Misbranding of Venus Tablets. U. S. v. David Clarence Overpeck (Thoro Sales Service). Plea of nolo contendere. Fine, $50. (F. D. C. No. 5543. Sample Nos. 30305–E, 31965–E.)

The label of this product bore false and misleading claims regarding its efficacy in the control of weight, and the bottle occupied only approximately 55 percent of the capacity of the carton.

On February 26, 1942, the United States attorney for the Southern District of California filed an information against David Clarence Overpeck, trading as Thoro Sales Service at Los Angeles, Calif., alleging shipment on or about May 6 and September 22, 1940, from the State of California into the State of Illinois of quantities of Venus Tablets that were misbranded.

Analyses of samples of the article showed that it was essentially a vegetable laxative containing rhubarb root, kelp, and other vegetable tissues.

The article was alleged to be misbranded: (1) In that the designation "Venus Tablets" on the bottle label and carton, the design of a slender woman, and

statements in an accompanying booklet were misleading since they created the impression that by virtue of its physiological activity when used as a part of the Venus Method of Weight Control, it would be of substantial effect in the control of body weight in enabling one to arrive at a satisfactory weight, in enabling one to obtain an ideal and slender form and that when so used it was appropriate and efficacious in the treatment of obesity; whereas it would not be efficacious for such purposes. (2) In that its container (carton) was so made, formed, or filled as to be misleading.

On March 30, 1942, the defendant entered a plea of nolo contendere and the court imposed a fine of $25 on each of the two counts.

685. Misbranding of Sixty Minute Worm Expeller. U. S. v. Raymond G. Burfeind (Chemical Products Co.). Plea of guilty. Fine, $25. (F. D. C. No. 4111. Sample No. 26103-E.)

The labeling of this product, which was in capsule form, bore false and misleading representations regarding its efficacy in the treatment of worms in dogs and cats.

On June 10, 1941, the United States attorney for the District of Minnesota filed an information against Raymond G. Burfeind, trading as Chemical Products Co., Ellsworth, Minn., alleging shipment within the period from on or about May 11 to on or about May 29, 1940, from the State of Minnesota into the State of Oregon of a quantity of worm expeller which was misbranded.

Analyses showed that the article consisted essentially of kamala, areca nuts, charcoal, a small amount of sugar, iron sulfate, and a minute amount of nicotine.

It was alleged to be misbranded in that statements in the labeling which represented and suggested that it was a safe, sure quick-action worm expeller and would be efficacious to expel worms from dogs, puppies, cats, and kittens in 60 minutes; that it would be efficacious in the treatment of tapeworms and stomach worms; that if used every 4 months, it would be efficacious to free dogs and puppies of worms; that it would reduce the danger of distemper, paralysis, eczema, and kindred diseases to a minimum; that it would be efficacious to worm breeding bitches, to worm puppies and "cut losses to practically no losses at all," and to keep older dogs free from worms; would reduce the danger of fits, paralysis, distemper, eczema, and kindred diseases to a minimum if used every 4 months; and would worm cats and assist in keeping them in good health if used every 4 months were false and misleading since it was not a safe, sure, quick-action worm expeller but was toxic and might be harmful and would not be efficacious for the aforementioned purposes.

It was alleged to be misbranded further in that the labeling was misleading, since it failed to reveal the fact material in the light of the representations made and suggested therein, and material with respect to the consequences which might result from its use, under conditions prescribed in the labeling or under such conditions of use as are customary or usual, namely, the fact that it was toxic and might be harmful.

On January 27, 1942, the defendant having entered a plea of guilty, the court imposed a fine of 25.

686. Misbranding of Dr. Gordshell's Salve. U. S. v. 16 Dozen Jars and 53 Jars of Dr. Gordshell's Salve. (F. D. C. No. 6650. Sample Nos. 59078-E, 59079-E, 59088-E.)

On January 2, 1942, the United States attorney for the District of Columbia filed a libel against 16 dozen 1-ounce jars and 53 2-ounce jars of Dr. Gordshell's Salve at Washington, D. C., alleging that the article had been shipped on or about September 23, October 17, and November 28, 1941, by the Gordshell Chemical Co. from Baltimore, Md.; and charging that it was misbranded.

Analyses of samples showed that the article consisted of fatty, waxy, and resinous materials containing volatile oils and a trace of alkaloid (not more than 0.002 percent).

The article was alleged to be misbranded: (1) In that the statement on the jar labels and cartons, "Contains: Stramonium Alk. .05%," was false and misleading since it contained not more than 0.002 percent, if any, stramonium alkaloids. (2) In that statements appearing in the labeling which suggested and represented that it was efficacious for skin irritations and boils and that its ingredients possessed unusual properties for promoting health were false and misleading since when used as directed, it would not be efficacious for treatment of many types of skin irritation, it would not be efficacious for boils, and its ingredients did not possess unusual qualities for promoting healing. (3) In that the labeling failed to

bear the common or usual name of each active ingredient since the statement on the jar labels and the individual carton labels, "Contains: Stramonium Alk. .05%, Oil of Sassafras, Elder Flowers, Bayberry, Rosin, Beeswax, in a Suitable Base," was not a statement of the active ingredients.

On February 27, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

687. Misbranding of Savol and Savol Cream. U. S. v. 2⅛ Dozen Packages of Savol and 2⅛ Dozen Packages of Savol Cream. Default decree of condemnation and destruction. (F. D. C. Nos. 5901, 5902. Sample Nos. 64167–E, 64168–E.)

The labels of both of these products, in addition to bearing false and misleading claims, failed to bear the required ingredient and accurate quantity of contents statements. Furthermore, the cartons containing the bottles of Savol were unnecessarily large.

On September 29, 1941, the United States attorney for the Northern District of Ohio filed libels against the above-named products at Youngstown, Ohio, alleging that they had been shipped within the period from on or about June 23 to on or about August 13, 1941, by the Savol Chemical Co. from Mercer, Pa.; and charging that they were misbranded.

Analyses of samples of the articles showed that Savol consisted essentially of cresols, alkali soaps and water; and that the Savol Cream consisted essentially of zinc oxide, barium sulfate, petrolatum, and perfume materials.

The Savol was alleged to be misbranded (1) in that statements in the labeling which represented that it would be efficacious to protect against and prevent serious infection; that it would be efficacious in the treatment of bites of animals, open sores, irritation of the throat or nasal passages arising from catarrh, hay fever, or kindred ills; that it would minimize the possibility of infected sores, abscesses, boils, felons, and all complications due to infections, and that it would always be helpful and often curative, were false and misleading since it would not be efficacious for such purposes; and (2) in that its container was so made, formed, or filled as to be misleading.

The Savol Cream was alleged to be misbranded in that statements in the labeling which represented that it was an antiseptic and would be efficacious in the treatment of cuts, boils, felons, sores, ulcers, itching and all forms of piles, eczema, skin affections in general, and bites of animals; that it would be efficacious for the after treatment of carbuncles and erysipelas and in the treatment of sore throat, croup, and enlarged glands when used on the neck, were false and misleading since it would not be efficacious for such purposes.

Both products were alleged to be misbranded (1) in that their labels failed to bear the common or usual names of the active ingredients; and (2) in that their labels failed to bear an accurate statement of the quantity of contents.

On November 26, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

688. Misbranding of Waft-Surgical. U. S. v. 11 Gallon Bottles of Waft-Surgical. Default decree of condemnation and destruction. (F. D. C. No. 5810. Sample No. 49661–E.)

The labeling of this product bore false and misleading antiseptic and therapeutic claims and also failed to bear the common or usual names of the active ingredients.

On September 22, 1941, the United States attorney for the Eastern District of Texas filed a libel against the above-named product at Rusk, Tex., alleging that the article had been shipped in interstate commerce from Springfield, Ill.; a portion on or about April 20, 1940, by Waft Products, Inc., and the remainder on or about June 13, 1941, by the Federal Cosmetic Sales Corporation; and charging that it was misbranded.

Analysis showed that the article consisted essentially of water and formaldehyde, with small amounts of terpineol and a yellow-green coloring material.

The article was alleged to be misbranded in that representations in the labeling that it had a phenol coefficient of 70, that it would be efficacious as an antiseptic, disinfectant, fungicide, germicide, parasiticide, in the dilutions suggested; that it would be of value as a wet dressing or application on wounds in the dilutions suggested; that it would inhibit disease producing micro-organisms and would be efficacious for sterilization of surgical instruments; that it would be efficacious for general prophylactic treatment; that it would be efficacious in the treatment of wounds and infections, would neutralize fetid odors; would control obnoxious odors incident to tissue breakdown due to cancer, gangrene, "infected amputations," pus drainage, fistulae, urinary fecal, etc.; that when used as a wet dress-

ing it would trap emanating odors; that it was efficacious as a douche for cancer and infections of the cervix and vagina; that because of its high phenol coefficiency it might be diluted 300 to 400 times and still retain its antiseptic properties; and that it would be efficacious as a safeguard against fungi and "parasitical infections" of animals, were false and misleading, since its phenol coefficient was less than 1 and it would not be efficacious for the purposes claimed. It was alleged to be misbranded further in that its label did not contain the common or usual names of the active ingredients.

On October 25, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

689. Misbranding of Lash's Bitters. U. S. v. 28 Bottles of Lash's Bitters. Default decree of condemnation and destruction. (F. D. C. No. 6772. Sample No. 85438–E.)

On January 31, 1942, the United States attorney for the District of Oregon filed a libel against the above-named product at Portland, Oreg., alleging that it had been shipped on or about October 27, 1941, by Lash, Inc., from Anaheim, Calif.; and charging that it was misbranded.

Analysis of a sample of the article showed that it was essentially a water-alcohol extract of laxative plant drugs such a cascara sagrada and senna.

It was alleged to be misbranded in that statements on the label which represented that it was a regulator, that it would exert a beneficial influence upon the digestive organs, that it was an adequate remedy for indigestion, headaches, and loss of appetite arising from imperfect digestion, and that its was an adequate treatment for chronic constipation were false and misleading since it would not be efficacious for such purposes. It was alleged to be misbranded further in that the following statements were false and misleading since frequent or continued use would be likely to result in a state of dependence upon laxatives to move the bowels: "The system does not become habituated to its use. Its properties do not cause the harsh after effects which may accompany cathartics."

On March 25, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

690. Misbranding of Todd's Capsules. U. S. v. 28 Packages and 11 Packages of Todd's Capsules. Default decree of condemnation and destruction. (F. D. C. No. 6307. Sample Nos. 79317–E, 79328–E.)

On December 1, 1941, the United States attorney for the Northern District of Ohio filed a libel against 28 packages each containing 6 yellow boxes of 50 capsules each; and 11 packages each containing 1 orange box, 2 green boxes, and 3 yellow boxes of 50 capsules each, at Canton, Ohio, alleging that the article had been shipped within the period from on or about August 16 to on or about November 21, 1941, by J. E. Todd, Inc., from Kenmore, N. Y.; and charging that it was misbranded.

Examination of samples of the article showed that the capsules consisted essentially of magnesium oxide (approximately 0.16 grains), calcium carbonate (approximately 2 grains), sodium bicarbonate varying in the different colored boxes from 2.1 to 3.8 grains, a gum resin such as olibanum, small proportions of an iron compound and sulfur, and sand varying from 2.5 to 4.3 grains per capsule.

The article was alleged to be misbranded in that the following statements on the label, "For relief of conditions of excessive acidity in the human body and the gradual alleviation in that way of aches and pains that may be symptoms of or associated with those conditions, which symptoms may be popularly referred to as 'rheumatic' * * * Caution: No immediate relief may be expected from these capsules and they should be allowed a reasonable time, according to particular conditions in each indicated case, for the best possible results," were false and misleading since it was not an adequate treatment for conditions and symptoms popularly referred to as "Rheumatic" and would not effect relief from such conditions after a reasonable, or after any other, time.

On February 26, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

691. Misbranding of Hi-V Vitamins capsules. U. S. v. 48 Dozen and 24 Dozen Cartons of Hi-V Vitamins. Consent decree of condemnation. Product ordered released under bond to be relabeled. (F. D. C. No. 6927. Sample No. 87506–E.)

The labeling of this product bore false and misleading claims regarding its efficacy to restore and maintain health and prevent or correct disease conditions, and represented that it contained all the vitamins essential in normal nutrition;

but it did not contain riboflavin or nicotinic acid, two substances whose absence from the diet may be the cause of vitamin deficiency diseases.

On February 25, 1942, the United States attorney for the District of Maryland filed a libel against 72 dozen cartons of Hi–V Vitamins at Baltimore, Md., alleging that the article had been shipped on or about January 19, 1942, by the Hi–V Vitamin Corporation from New York, N. Y.; and charging that it was misbranded. It was labeled in part: "6250 U. S. P. Units Vitamin A (from fish liver oils) 350 Int. Units Vitamin B_1 (Thiamin chloride) 300 U. S. P. Units Vitamin C (Ascorbic acid) 625 U. S. P. Units Vitamin D (Irradiated Ergosterol)."

The article was alleged to be misbranded in that statements in an accompanying circular entitled "What You should know about Vitamins," representing, suggesting, and creating in the mind of the reader the impression that health could be assured by its consumption; that the average individual requires vitamin supplements of the type that it supplied in order to obtain maximum health: that the average individual is likely to be suffering from lack of vitality, lack of energy, poor appetite, and impaired digestion because of inadequate vitamin intake from his food; that its consumption as directed, in the majority of cases, would prevent or correct the disease conditions resulting from inadequate vitamin intake; and that it contained all the vitamins essential in normal nutrition, were false and misleading since it would not fulfill the promises implied and it did not contain riboflavin or nicotinic acid, two vitamins essential in normal nutrition.

It also was alleged to be misbranded under the provisions of the law applicable to foods, as reported in F. N. J. No. 3644.

On March 26, 1942, the Hi–V Vitamin Corporation having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond to be relabeled. On the same date the product was relabeled by removal from the carton of the circular entitled "What You should know about Vitamins."

692. Misbranding of Tu-Way Massagers. U. S. v. 15 Tu-Way Massagers. Default decree of condemnation and destruction. (F. D. C. No. 6268. Sample No. 66325–E.)

This massaging device consisted of a series of rubber-covered disks, attached to a handle, which were to be rolled over portions of the body. It would not be efficacious to reduce weight or to stimulate the activity of the liver, as claimed in the labeling.

On December 2, 1941, the United States attorney for the Northern District of Illinois filed a libel against 15 Tu-Way Massagers at Chicago, Ill., alleging that the article had been shipped in interstate commerce on or about August 21, 1941, by the Edw. W. Arnold Co. from Logansport, Ind.; and charging that it was misbranded.

The article was alleged to be misbranded in that statements appearing in the accompanying circular which represented that it was founded on an exact scientific principle and would positively reduce the fat spots and beautify the body and figure; that it would bring about a gradual fat reduction and cause flabby fat to disappear; would break down the fat in a natural and healthful way; would break down the fatty deposits so that they would be oxidized (burned up) within the body, with the result that the residue would be carried away by the blood stream and eliminated through the organs of elimination, leaving the flesh more firm and solid; that it would be wonderfully soothing and strengthening to tired, aching neck, and shoulders and would stimulate the circulation and relieve congested or tight feeling often felt between the shoulders; that it would be efficacious in correcting fleshy, corpulent, and pendulous abdomens; and would stimulate activity of the liver; were false and misleading since it would not be efficacious for such purposes.

On January 21, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

693. Misbranding of Ultrasol. U. S. v. 2 Kits and 6 Kits of Ultrasol. Default decree of condemnation and destruction. (F. D. C. No. 6062. Sample No. 74710–E.)

The labeling of this product bore false and misleading representations regarding its efficacy to promote hair growth and to prevent hair loss and premature graying.

On or about October 25, 1941, the United States attorney for the District of New Jersey filed a libel against 8 kits of Ultrasol at East Orange, N. J., alleging that the article had been shipped in interstate commerce on or about September

30, 1941, by Post Institute Sales Corporation from Newburgh, N. Y.; and charging that it was misbranded.

Examination showed that the kits contained, among other items, a bottle of Ultrasol Fluid, cartons of Ultrasol Hair Bath, and a leaflet entitled "How to apply the Ultrasol Standard Treatment." Analysis of the Ultrasol Fluid showed that it consisted essentially of light mineral oil, oxyquinoline (0.12 gram per 100 cubic centimeters), organic substances including cholesterol and perfume. Analysis of the Ultrasol Hair Bath showed that it consisted essentially of a wetting agent, such as sodium lauryl sulfate, a small proportion of cholesterol, and other organic material.

The article was alleged to be misbranded in that statements on the kit label, the bottle label of the Ultrasol Fluid, upon the carton label of the Hair Bath, in the aforesaid leaflet, and in a booklet entitled "The Cultivation of Luxuriant Hair," which had been incorporated into the leaflet by the legend "For exposition of theory see our booklet 'The Cultivation of Luxuriant Hair'," which represented and suggested that it would promote luxurious hair and scalp hygiene; that it would remove dandruff and neo-keratin, and help check excessive hair loss and combat premature graying; that it would bring about a condition under which the natural hair-growing process would be unimpeded and natural hair growth would become possible; that it would clear away the neo-keratin, enabling the dormant hair within the scalp to become free to resume normal growth and the fuzz to develop into full-size hair; that it would remove obstruction to the development of fuzz or thin short hair; would stop abnormal hair loss; free the scalp from dandruff; make dull, dry, faded hair become brilliant; that new hair would be produced on gray heads, which frequently would be of the original shade, thus indicating that it would prevent graying; would revive limp, dull, scanty "impossible" hair without strong rinses, scalp manipulation, or tiring massage; would strengthen the hair for lasting, artistic permanent waving; would normalize dry or oily scalp; would give dyed hair an even, "refined" luster; and would keep the scalp clean and free from dandruff, were false and misleading since it would not be efficacious for such purposes.

On January 29, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

694. Misbranding of Beacon's Stokade, Beacon's Cam-Pho-Spray, Beacon's Poultry Liquid, Beacon's Chexal, Beacon's Fowl-Ade, and Beacon's Swinade. U. S. v. 12 Packages of Beacon's Stokade (and 5 other seizures of Beacon's veterinary preparations). Default decrees of condemnation and destruction. (F. D. C. Nos. 6118 to 6123, incl. Sample Nos. 58221-E, 58222-E, 58223-E, 58656-E, 58657-E, 58658-E.)

On November 4, 1941, the United States attorney for the District of Minnesota filed libels against 12 packages of Beacon's Stokade, 24 bottles of Beacon's Cam-Pho Spray, 16 bottles of Beacon's Poultry Liquid, 32 cans of Beacon's Chexal, 30 cans of Beacon's Fowl-Ade, and 43 cans of Beacon's Swinade at St. Cloud, Minn., alleging that the articles had been shipped in interstate commerce on or about April 21 and 28, 1941, by the Beacon Laboratories from Fond du Lac, Wis.; and charging that they were misbranded.

Analysis of Beacon's Stokade showed that it consisted essentially of plant materials including nux vomica, gentian, pokeroot, quassia bark, tamarack bark, caraway seed, ginger and fenugreek, iron oxide, ferric citrate, calcium lactate, and charcoal. It was alleged to be misbranded in that the statements in the labeling which represented that it was a stimulant and would assist in the digestion and assimilation of feed by exciting the flow of digestive juices, that it was effective as a general tonic, would be of value at freshening time and that another drug, namely, Chexal, would be an efficacious treatment for scours in livestock, were false and misleading since the articles when used as directed would not be efficacious for such purposes.

Analysis of the Cam-Pho-Spray showed that it consisted essentially of volatile oils including camphor and eucalyptus oil, soap, creosote, and pine oil. It was alleged to be misbranded in that statements in the labeling which represented that it was an antiseptic when used as an inhalant were false and misleading since when used as directed, it was not an antiseptic.

Analysis of the Poultry Liquid showed that it consisted essentially of potassium salts including dichromate, chlorate, and nitrate, Epsom salt, and sugar dissolved in water. It was alleged to be misbranded in that statements in the labeling which represented that it was an intestinal antiseptic for all fowl were false and misleading since when used as directed in the labeling, it would not be efficacious for such purposes.

Analysis of Beacon's Chexal showed that it consisted essentially of salol, tannic acid, bismuth subnitrate and subcarbonate (approximately 7.7 percent), sodium bicarbonate (15.5 percent, calcium carbonate (66.9 percent), and magnesium carbonate (5.79 percent). It was alleged to be misbranded in that statements in the labeling which represented that it would help retard scour losses in all livestock, that it was an excellent tonic and stimulant, were false and misleading since when used as directed in the labeling, it would not be efficacious for such purposes.

Analysis of Beacon's Fowl-Ade showed that it consisted essentially of copper sulfate (41.84 percent), kamala resins (15.6 percent), nicotine sulfate, nux vomica, iron sulfate, and anise. Its package was materially larger than was necessary to hold its contents. It was alleged to be misbranded in that statements in the labeling which represented that it was a "fowl-ade" for chickens, turkeys, ducks, and geese of all ages, were false and misleading since when used as directed in the labeling, it would not be efficacious for such purposes. It was alleged to be misbranded further in that its container was so made, formed, and filled as to be misleading.

Analysis of Beacon's Swinade showed that it consisted essentially of hydrated lime, sulfur (10.8 percent), iron sulfate, and plant material including nux vomica, American wormseed, and corn meal. It was alleged to be misbranded in that statements in the labeling which represented that it was efficacious in the treatment of large roundworms and that another drug, namely, Chexal, would be efficacious in the treatment of scours in livestock, were false and misleading since the articles when used as directed would not be efficacious for such purposes.

On March 4, 1942, no claimant having appeared, judgments of condemnation were entered and the products were ordered destroyed.

695. Misbranding of Formula A–1. U. S. v. 42 Gallon Cans of Formula A–1. Default decree of condemnation. Product destroyed. (F. D. C. No. 6314. Sample No. 76456–E.)

On December 2, 1941, the United States attorney for the District of South Dakota filed a libel against the above-named product at Sioux Falls, S. Dak., alleging that in the months of September and October, 1941, the article had been shipped by Stanley S. Steinharter from Cincinnati, Ohio; and charging that it was misbranded.

Analysis of a sample of the article showed that it consisted essentially of creosote, sodium salts of cresols, a small proportion of sodium hydroxide, a trace of an arsenic compound, extracts of plant drugs, sugar, and water.

It was alleged to be misbranded in that statements in the labeling representing that it would be efficacious in the treatment of enteritis or dysentery due to bacterial infection of swine, cattle, and poultry, were false and misleading since it would not be efficacious for such purposes.

On January 5, 1942, no claimant having appeared, judgment of condemnation was entered and the product was subsequently destroyed.

DRUGS IN DECEPTIVE CONTAINERS

696. Misbranding of Caulk Mercitan Lotion. U. S. v. 66 Packages of Caulk Mercitan Lotion. Default decree of condemnation and destruction. (F. D. C. No. 6754. Sample No. 54182–E.)

This product was packed in triangular-shaped bottles, each of which was placed in a square cardboard container. The 8-ounce bottles occupied approximately 43 percent of the capacity of the containers and the 3½-ounce bottles occupied approximately 44 percent of the capacity of the containers.

On January 24, 1942, the United States attorney for the Eastern District of Pennsylvania filed a libel against 24 8-ounce packages and 42 3½-ounce packages of the above-named product at Philadelphia, Pa., alleging that it had been shipped on or about November 17 and December 23, 1941, by the L. D. Caulk Co. from Milford, Del.; and charging that it was misbranded in that its container was so made, formed, or filled as to be misleading.

On February 16, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

697. Misbranding of Wemett's Salve. U. S. v. 115 Packages of Wemett's Salve. Default decree of condemnation. Product ordered destroyed or delivered to a charitable institution. (F. D. C. No. 6692. Sample No. 85427–E.)

The tube in which this product was packed occupied only about 14 percent of the capacity of the carton.

On January 13, 1942, the United States attorney for the District of Oregon filed a libel against 115 ¼-ounce packages of Wemett's Salve at Portland, Oreg., alleging that the article had been shipped on or about August 28 and October 1, 1941, by F. J. Wemett from Los Angeles, Calif.; and charging that it was misbranded in that its container was so made, formed, and filled as to be misleading.

On March 25, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed, or delivered to a charitable institution.

NONSTERILE SURGICAL DRESSINGS

698. Adulteration and misbranding of sutures. U. S. v. 32 Packages of Sutures. Default decree of condemnation and destruction. (F. D. C. No. 6762. Sample No. 71511–E.)

On January 26, 1942, the United States attorney for the Southern District of Iowa filed a libel against the above-named product at Des Moines, Iowa, alleging that it had been shipped on or about September 17, 1941, by Davis Sutures, Inc., from Chicago, Ill.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, but its purity fell below the standard set forth in the pharmacopoeia since it was not sterile. It was alleged to be misbranded in that the statement in the labeling, "Guaranty Davis Sutures are guaranteed to be sterile," was false and misleading since it was not sterile but was contaminated with viable aerobic and anaerobic or facultative anaerobic micro-organisms, including spore-bearing and gas-producing micro-organisms.

On February 28, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

699. Misbranding of finger compresses. U. S. v. 1,344 Packages of Quick Strips Finger Compresses. Default decree of condemnation and destruction. (F. D. C. No. 6901. Sample Nos. 92009–E, 92010–E.)

On February 20, 1942, the United States attorney for the Southern District of California filed a libel against the above-named product at Los Angeles, Calif., alleging that it had been shipped on or about January 23, 1942, by the Quick Manufacturing Co. from Chicago, Ill.; and charging that it was misbranded.

The article was alleged to be misbranded in that designs showing application of the strips to the finger and the statements, "Place Medicated Pad over Injury," "Press Edges Together," "Wrap Around Finger," and "Medicated With Boric Acid or Iodochrome," were misleading when applied to a bandage which was contaminated with viable micro-organisms; and in that such designs and statements suggested that it would be suitable for first aid purposes; whereas it was not.

On March 19, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

700. Adulteration and misbranding of Hill's Swabbed Applicators with Tongue Blade. U. S. v. 76 Cartons of Hill's Swabbed Applicators with Tongue Blade. (F. D. C. No. 6849. Sample No. 70098–E.)

On or about March 2, 1942, the United States attorney for the Southern District of Florida filed a libel against 76 cartons of the above-named product at Jacksonville, Fla., alleging that it had been shipped on or about November 27, 1941, by the Wetmore-Century Corporation from New York, N. Y.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that its purity and quality fell below that which it purported or was represented to possess, namely, (glassine envelope) "sterilized," since it was not sterile but was contaminated with aerobic, anaerobic, or facultative anaerobic micro-organisms.

It was alleged to be misbranded in that the following statements in the labeling, (envelope) "Sterilized Applicators * * * Sterilized After Packing," and (carton) "The Modern Way of Treating sore throats, cuts, wounds, ear and nose ailments. The Ideal Way of safeguarding your health * * * For eye, ear and nose treatment * * * especially useful to mothers treating infants * * * specially made for Throat Treatment," were false and misleading when applied to an article that was not sterile but was contaminated with viable micro-organisms.

On March 21, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

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PRODUCTS

SHIPPERS AND MANUFACTURERS

U. S. GOVERNMENT PRINTING OFFICE: 1943

D. D. N. J., F. D. C. 701–750 Issued April 1943

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

701–750

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

WATSON B. MILLER, *Acting Administrator, Federal Security Agency.*

WASHINGTON, D. C., *February 12, 1943.*

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DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

701. Action to restrain interstate shipment of Alcoban, a misbranded drug. U. S. v. Maffett Sales Corporation, Frank L. Wilson, Nell B. Wilson, and Reuel K. Yount. Temporary restraining order entered. Default order granting permanent injunction. (Inj. No. 17.)

On October 20, 1941, the United States attorney for the Western District of Washington filed a complaint against the Maffet Sales Corporation and Frank L. Wilson, Nell B. Wilson, and Reuel K. Yount, Seattle, Wash., alleging that the defendants for many years past, had been engaged in the sale and distribution of an article of drugs called Alcoban; that the article was sold by the defendants in cartons which bore the printed statement, "An Aid in Curbing the Liquor Habit," and was accompanied by a circular which contained, among others, the representation that it was an aid in curing the liquor habit, and directions that the contents of 1 capsule should be given every 15 to 20 minutes until 3 capsules were taken; that, if vomiting occurred, this should be regarded as a proper dosage; that, if no vomiting occurred on the 1-capsule per drink basis, the dosage should be doubled, and if vomiting then occurred this should be considered the correct dosage; and that, if no vomiting occurred after the consumption of three single-dose drinks and two double-dose drinks, the treatment should be discontinued. The complaint alleged further that the statements in the labeling were false and misleading since the article did not constitute an appropriate remedy for the purposes stated and recommended; that the use and administration of the drug in the dosage and with the frequency and duration prescribed, recommended, and suggested in the labeling was dangerous to health, and that consequently the product was misbranded. The complaint alleged further that

the defendants at that time were introducing and delivering the said drug for introduction into interstate commerce and prayed that judgment and decree be entered permanently restraining and enjoining them and all acting upon their behalf from continuing to do so; and prayed that a preliminary injunction be granted restraining the defendants during the pendency of the action.

On November 10, 1941, the court granted a temporary restraining order in accordance with the prayer of the complaint. On June 9, 1942, the defendants then being in default, judgment was entered permanently and forever enjoining and restraining them from directly or indirectly introducing or delivering for introduction said drug into interstate commerce.

702. Misbranding of Lambert's Powders. U. S. v. Claude M. Stanley (Stanley Drug Co.). Plea of guilty. Fine, $50. (F. D. C. No. 4161. Sample No. 38881–E.)

This product when used according to directions on the label, would be dangerous to health, the label failed to bear adequate warning statements, and it also contained false and misleading claims.

On November 10, 1941, the United States attorney for the District of Minnesota filed an information against Claude M. Stanley, trading as the Stanley Drug Co. at Minneapolis, Minn., alleging shipment on or about July 19, 1940, from the State of Minnesota into the State of Wisconsin of a quantity of Lambert's Powders that were misbranded.

Analysis of a sample of the article showed that each powder contained acetanilid (2½ grains), aspirin (5 grains), and salol (2½ grains).

The article was alleged to be misbranded: (1) In that it was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling, i. e., "Directions * * * Adult Dose: One before each meal and one at bedtime." (2) In that its labeling failed to bear adequate warnings against use by children where its use might be dangerous to health, or against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users since each powder contained approximately 2½ grains of acetanilid, and the labeling did not bear a warning that frequent or continuous use might cause serious blood disturbances, anemia, collapse, or a dependence on the drug, and that it should not be given to children. (3) In that the statement (carton) "muscular aches and body pains, lumbago," was false and misleading since it represented that the drug was efficacious in the treatment of muscular aches, body pains, and lumbago; whereas it was not efficacious for such purposes.

On March 3, 1942, the defendant entered a plea of guilty and the court imposed a fine of $50.

703. Misbranding of a.m. Solution. U. S. v. 7½ Dozen Packages of a.m. Solution. Default decree of condemnation and destruction. (F. D. C. No. 6839. Sample No. 79171–E.)

This product contained chrysarobin and would be dangerous to health when used according to directions. Its label also contained false and misleading therapeutic claims.

On February 13, 1942, the United States attorney for the Middle District of Tennessee filed a libel against the above-named product at Nashville, Tenn., alleging that it had been shipped on or about November 13, 1941, and January 14, 1942, by the Kenton Pharmacal Co., Inc., from Covington, Ky.; and charging that it was misbranded.

Analysis of a sample of the article showed that it consisted essentially of chrysarobin (approximately 0.66 grain per fluid ounce), salicylic acid, benzoic acid, alcohol, and a volatile oil.

The article was alleged to be misbranded: (1) In that it was dangerous to health when used in the dosage or with the frequency or duration prescribed or recommended in the labeling. (2) In that the following statements, "For the relief of itching and discomfort of Athlete's Foot (Dermatophytosis), Ringworm, Insect Bites, Impetigo, externally caused Eczema, Rashes and Pimples, and other forms of local skin irritations," were false and misleading since they represented and suggested that when used as directed it constituted a safe and efficacious treatment for the relief of the itching torment and discomfort of athlete's foot and other skin irritations named above; whereas it was not safe when used as directed and was not an efficacious treatment for such conditions.

On April 9, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS [1]

704. Misbranding of Dickson's Laxative Rheumatic Diruatica. U. S. v. 15 Bottles of Dickson's Laxative Rheumatic Diruatica. Default decree of condemnation and destruction. (F. D. C. No. 6899. Sample No. 71670–E.)

The labeling of this product, in addition to failure to bear adequate directions for use and such adequate warnings as are necessary for the protection of users, also bore false and misleading curative and therapeutic claims.

On February 27, 1942, the United States attorney for the Eastern District of Arkansas filed a libel against the above-named drug product at Blytheville, Ark., alleging that it had been shipped in interstate commerce on or about November 7, 1941, by A. H. Dickson from Memphis, Tenn.; and charging that it was misbranded.

Analysis showed that the article consisted essentially of Epsom salt, methenamine, sodium salicylate, sodium benzoate, salicylic acid, methyl salicylate, and was colored with caramel.

The article was alleged to be misbranded: (1) In that the labeling did not bear adequate directions for use since there was no limitation as to duration of use and the statement "Dose—Tablespoonful four times a day in a glass of water" implied that it was to be taken continuously; whereas a laxative should be taken only occasionally. (2) In that the labeling failed to bear adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health or adequate warnings against duration of administration, in such manner and form as are necessary for the protection of users since it failed to bear a warning that the drug should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis are present and that frequent or continued use might result in dependence upon laxatives. (3) In that statements on the label, "Rheumatic Diruatica * * * Recommended for Rheumatic Urinary and Constipated Conditions," were false and misleading since they represented and suggested that it would be efficacious for rheumatic, urinary, and all constipated conditions; whereas it would not be efficacious for such conditions.

On May 4, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

705. Misbranding of Dromgooles Bitters. U. S. v. 13 Bottles and 7 Bottles of Dromgooles Bitters. Default decree of condemnation and destruction. (F. D. C. No. 7011. Sample Nos. 73185–E, 73186–E.)

The labeling of this product bore no directions for use and bore false and misleading representations regarding its curative and therapeutic efficacy. Furthermore, the designation "Bitters" was not appropriate for a drug of this type.

On March 16, 1942 the United States attorney for the Western District of Oklahoma filed a libel against 20 bottles of Dromgooles Bitters at Oklahoma City, Okla., alleging that the article had been shipped in interstate commerce on or about January 2, 1942, by the McCullough Drug Co. from Lawrenceburg, Ind.; and charging that it was misbranded.

Analysis showed that the article consisted essentially of extracts of plant drugs including an alkaloid-bearing drug and a laxative drug, iron and ammonium citrate, alcohol, and water. It had an aromatic and astringent but not a bitter taste.

The article was alleged to be misbranded (1) in that its labeling failed to bear any directions for use; and (2) in that the statements on the labels, (both lots) "Bitters * * * Uterine Tonic, Sedative and Antispasmodic Aid in the relief of Periodic Pain and Distress" and (13 bottles) "Discontinue treatment when acute symptoms have subsided," were false and misleading since it was not a bitters, was not efficacious as a uterine tonic or sedative nor as an antispasmodic aid in the relief of periodic pain and distress, and (13 bottles) it would not be efficacious in the treatment of acute symptoms of such conditions.

On April 29, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

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[1] See also No. 702 and soda in No. 720.

706. Misbranding of Greenawalt's Compound Dandelion Liver Disks. U. S. v. 164 Packages of Greenawalt's Compound Dandelion Liver Disks. Default decree of condemnation and destruction. (F. D. C. No. 4937. Sample No. 50252–E.)

The labeling of this product, a laxative, failed to bear adequate directions for use and adequate warnings, and bore false and misleading claims regarding its therapeutic and curative efficacy. The labeling also falsely implied that the physiological activity of the article was derived from dandelion, and failed to bear the ingredients statement, including the quantity or proportion of strychnine and belladonna alkaloids.

On June 14, 1941, the United States attorney for the Middle District of Pennsylvania filed a libel against the above-named product at Chambersburg, Pa., alleging that it had been shipped in interstate commerce on or about March 26, 1941, from Norwich, N. Y., to Chambersburg, Pa., and that it had been removed from the original container and repacked and relabeled—the labeling including a circular by William G. Greenawalt; and charging that as so repacked and relabeled it was misbranded.

Analysis showed that the article consisted essentially of laxative plant drugs, such as podophyllum and aloes, together with small amounts of belladonna and nux vomica (strychnine) alkaloids.

The article was alleged to be misbranded: (1) In that its labeling did not bear adequate directions for use, since the directions, (label) "Dose—1 or 2 at night. When 1 is too active on the bowels, divide a disk and take half," and (circular) "Usual Dose: One or two at bedtime. Should one be too active on the bowels, take half a disk. They can easily be cut in half. For children, usually half a Disk is sufficient," provided for an indefinite and continued use of a laxative which was inappropriate. (2) In that the label failed to bear adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users, since the labeling failed to warn that a laxative should not be taken when suffering from nausea, vomiting, abdominal pain, or other symptoms of appendicitis; that frequent or continued use might result in dependence upon laxatives; and that the use of an article containing strychnine might be especially dangerous to children and elderly persons and that not more than the recommended dosage should be taken. (3) In that the label did not bear the common or usual names of the active ingredients or a statement of the quantity or proportion of strychnine and belladonna alkaloids contained in the article. (4) In that statements in the labeling which implied that its therapeutic activity was derived from dandelion and which represented that it would relieve biliousness, clear the complexion, clear sallow skin, tone the liver and stomach and clean coated tongue, prevent dizziness and vertigo, stimulate the liver, remove pimples and blotches, improve the condition of the blood, tone up the whole system, relieve liver trouble, and that it was an excellent vegetable remedy for biliousness, dizziness, and stomach trouble caused by inactivity of the liver, were false and misleading since it did not depend upon dandelion for its therapeutic activity and it would not be efficacious for the purposes claimed.

On September 23, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

707. Misbranding of Kalis Capsules. U. S. v. 2¾ Dozen Packages and 9¾ Dozen Packages of Kalis Capsules. Default decree of condemnation and destruction. (F. D. C. No. 7005. Sample No. 71403–E.)

This product consisted essentially of acetanilid, and laxative plant drugs including podophyllin and cascara sagrada, but the labeling failed to bear adequate warning statements required for a drug of this type.

On March 6, 1942, the United States attorney for the Eastern District of Missouri filed a libel against the above-named product at St. Louis, Mo., alleging that it had been shipped on or about November 6 and December 5, 1941, by Kalis Products from Ottumwa, Iowa; and charging that it was misbranded.

The article was alleged to be misbranded in that the labeling failed to bear adequate warnings against use in those pathological conditions where its use might be dangerous to health, since it failed to warn that the drug should not be taken when nausea, vomiting, abdominal pain, or other symptoms of appendicitis are present; and it also failed to bear warnings against unsafe methods or duration of administration, since it failed to warn that frequent

or continued use might be dangerous, causing serious blood diseases, anemia, collapse, or dependence on the drug.

On April 7, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

708. Misbranding of Lanoton for Women. U. S. v. 53 Packages of Lanoton for Women. Default decree of condemnation and destruction. (F. D. C. 6980. Sample No. 83608–E.)

The labeling of this product failed to bear adequate directions for use and such adequate warnings as are necessary for the protection of users. The labeling also created the misleading impression that the article was of particular value to women.

On March 7, 1942, the United States attorney for the Eastern District of Texas filed a libel against 53 packages of the above-named product at Marshall, Tex., alleging that it had been shipped in interstate commerce on or about January 10, 1942, by the National Medicine Co. from Nashville, Tenn.; and charging that it was misbranded.

The article was alleged to be misbranded (1) in that it did not bear adequate directions for use since the labeling provided for frequent and continual administration, whereas the directions for a laxative should provide that it be taken only occasionally and when needed; (2) in that the labeling failed to bear adequate warnings against use in those pathological conditions where its use might be dangerous to health, and failed to bear adequate warnings against unsafe duration of administration; and (3) in that its label was misleading since it represented and suggested that the article was especially adaptable for use by women, whereas its effect would be the same on both men and women.

On May 5, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

709. Misbranding of solution of citrate of magnesia. U. S. v. 1,434 Bottles of Citrate of Magnesia. Default decree of condemnation. Product ordered delivered to a charitable institution. (F. D. C. No. 7421. Sample No. 78814–E.)

The labeling of this product failed to bear adequate warnings; to give the name and place of business of the manufacturer, packer, or distributor; and to bear an accurate statement of the quantity of contents.

On April 30, 1942, the United States attorney for the Western District of Pennsylvania filed a libel against 1,434 bottles of citrate of magnesia at Pittsburgh, Pa., alleging that the article had been shipped in interstate commerce on or about March 2, 1942, by S. D. C. Laboratories, Inc., from Buffalo, N. Y.; and charging that it was misbranded.

The article was alleged to be misbranded in that (1) its labeling failed to bear adequate warnings against use in those pathological conditions where its use might be dangerous to health or against unsafe duration of administration in such manner and form as are necessary for the protection of users, since there was no warning that it should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis are present, or that frequent or continued use might result in dependence on laxatives to move the bowels; (2) it failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; and (3) in that it was in package form and its label failed to bear an accurate statement of the quantity of the contents.

On May 19, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered delivered to a charitable institution.

710. Misbranding of Nurito. U. S. v. 75 Packages of Nurito. Default decree of condemnation and destruction. (F. D. C. No. 6994. Sample No. 83387–E.)

This product contained ⅓ gram of phenolphthalein, a laxative drug, per powder; and its labeling failed to bear adequate directions for use and such adequate warnings as are necessary for the protection of the user.

On March 14, 1942, the United States attorney for the Eastern District of Louisiana filed a libel against 75 packages of Nurito at New Orleans, La., alleging that the article had been shipped in interstate commerce on or about September 27, 1941, and January 23, 1942, by the Nurito Co. from Chicago, Ill.; and charging that it was misbranded.

The article was alleged to be misbranded: (1) In that the labeling did not bear adequate directions for use since the directions appearing in the labeling, "Take one powder, followed by full glass of water every three hours in indicated

conditions. Gradually reduce to two powders a day, one in morning and one at night, and then discontinue, according to conditions," provided for frequent use; whereas adequate directions for use of a laxative should provide that it be taken only occasionally, when needed. (2) In that the labeling failed to bear adequate warnings against use in those pathological conditions where its use might be dangerous to health and adequate warnings against unsafe duration of administration in such manner and form as are necessary for the protection of users since it failed to adequately warn the user that it should not be used when abdominal pain, nausea, vomiting or other symptoms of appendicitis are present and to warn that frequent or continued use might result in dependence upon laxatives.

On May 4, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

711. Misbranding of Pon-Tam-Pon and Glycerant. U. S. v. 57 Packages of Pon-Tam-Pon Medication A and 8 Packages of Pon-Tam-Pon Medication C. Default decree of condemnation and destruction. (F. D. C. No. 7152. Sample No. 23118–E.)

These products would be dangerous to health under certain pathological conditions and their labels failed to bear warnings of such danger. The labeling also contained false and misleading therapeutic claims.

On April 8, 1942, the United States attorney for the Northern District of California filed a libel against the above-named products at San Francisco, Calif., alleging that they had been shipped in interstate commerce on or about January 2, 1942, by the Pond Manufacturing Co. from Rutland, Vt.; and charging that they were misbranded.

Examination showed that each package contained a number of tampons and a tube of a product labeled "Glycerant." Examination of the Medication A tampon showed that it consisted essentially of a gelatin shell containing a jelly composed of glycerinated gelatin, boric acid, ichthyol, iodine, and a bundle of wool fibers. Examination of the Medication C tampon showed that it consisted essentially of a gelatin shell containing a jelly composed of glycerinated gelatin, boric acid, iodine, silver nitrate, and a bundle of wool fibers. Analysis of the Glycerant showed that it consisted essentially of boric acid in a jelly base.

The articles were alleged to be misbranded in that their labels failed to bear adequate warnings against use in those pathological conditions where their use might be dangerous to health, in such manner and form as are necessary for the protection of users, since the labeling failed to bear a warning that they should not be used in case of gonorrhea. They were alleged to be misbranded further in that the following statements in the labeling, "A tampon should be worn continuously and changed every 24 hours to obtain best results, although it gives support and is not offensive if worn 48 hours; but if profuse discharge is present tampon should be changed every 12 hours until discharge is relieved. * * * In case of prolapse and backward displacement of uterus the knee-chest position must be taken for the tampon's introduction," were false and misleading since they represented and suggested that the articles constituted effective treatments for discharge from the vagina and prolapse and backward displacement of the uterus; whereas they were not effective treatments for such conditions.

On May 22, 1942, no claimant having appeared, judgment of condemnation and destruction was entered and the products were ordered destroyed.

712. Misbranding of Shapley's Medicine for Acid or Sour Stomach. U. S. v. 21 Bottles of Shapley's Medicine for Acid or Sour Stomach. Default decree of condemnation and destruction. (F. D. C. No. 7325. Sample No. 71267–E.)

On April 15, 1942, the United States attorney for the Southern District of Iowa filed a libel against the above-named product at Davenport, Iowa, alleging that it had been shipped in interstate commerce on or about March 17, 1942, by the Shapley Drug Co., Inc., from Decatur, Ill.; and charging that it was misbranded.

Analysis showed that the article consisted essentially of extracts of plant drugs including rhubarb, alcohol, sugar, potassium carbonate, and water.

The article was alleged to be misbranded in that its labeling failed to bear adequate directions for use, since the directions on the label provided for continuous administration of an article which was a laxative and should therefore be taken only occasionally when needed. It was alleged to be misbranded further in that the labeling failed to bear adequate warnings against use in those pathological conditions where its use might be dangerous to health, since it failed to warn that the article was not to be taken when abdominal pains, nausea, vomit-

ing, or other symptoms of appendicitis were present; and the labeling failed to warn against unsafe methods or duration of administration since it failed to warn that frequent or continued use of the article might result in dependence on laxatives.

On May 15, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

713. Misbranding of Special Formula Tablets S. C. Purple. U. S. v. 51,000 Special Formula Tablets S. C. Purple. Default decree of condemnation and destruction. (F. D. C. No. 6902. Sample No. 40889–E.)

These tablets contained strychnine and the labeling failed to bear adequate directions for use and such adequate warnings as are necessary for the protection of users.

On February 20, 1942, the United States attorney for the Eastern District of Pennsylvania filed a libel against the above-named product at Philadelphia, Pa., alleging that the article had been shipped in interstate commerce on or about October 20, 1941, by the Purity Drug Co. from Passaic, N. J.; and charging that it was misbranded.

Analysis showed that the article contained yohimbé bark, a strychnine compound, a magnesium compound, zinc phosphide, and extracts of plant drugs, such as damiana.

The article was alleged to be misbranded in that its labeling failed to bear adequate directions for use since the statement on the drum label, "Dose: To be taken as directed by physician," did not constitute adequate directions for use. It was alleged to be misbranded further in that its labeling failed to bear such adequate warnings against use by children where its use might be dangerous to health, or against unsafe dosage or duration of administration, in such manner and form as are necessary for the protection of users since there were no warnings against frequent or long continued use under circumstances which might result in strychnine poisoning, nor was there any warning that the use of the article, because of its strychnine content, might be particularly dangerous to children and aged persons.

On May 1, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

714. Misbranding of Spicer's Compound. U. S. v. 117 Bottles of Spicer's Compound. Default decree of condemnation and destruction. (F. D. C. No. 6966. Sample No. 71519–E.)

This product was a laxative and its labeling failed to bear the required laxative warnings, failed to declare the strychnine and belladonna alkaloids present, failed to name the principal physiologically active ingredient under its common or usual name, and also bore false and misleading curative and therapeutic claims.

On March 2, 1942, the United States attorney for the Eastern District of Missouri filed a libel against 117 bottles of Spicer's Compound at St. Louis, Mo., alleging that the article had been shipped in interstate commerce on or about October 22, 1941, and January 21, 1942, by the Charles R. Spicer Co. from Memphis, Tenn.; and charging that it was misbranded.

Analysis showed that the article consisted essentially of a solution of Epsom salt (approximately 25 percent) with relatively small proportions of extracts of plant drugs including laxative plant drugs, and a small proportion of an iron salt, sweetened with saccharin and preserved with sodium benzoate.

The article was alleged to be misbranded (1) in that its labeling failed to bear adequate warnings against use in those pathological conditions where its use might be dangerous to health and against unsafe duration of administration in such manner and form as are necessary for the protection of users, since the statement on the label, "Caution—In case of severe abdominal pain, do not take a laxative" was not adequate to warn the purchaser against the use of the article in case of abdominal pain, nausea, vomiting, or other symptoms of appendicitis and did not warn the purchaser that frequent or continual use of the article might result in dependence upon laxatives to move the bowels; (2) in that the following statements in the labeling "Spicer's Compound * * * to aid in the relief of simple headache, heartburn, biliousness, sour stomach, gas in stomach and intestines due to occasional constipation" were misleading since they failed to reveal the material fact that the conditions mentioned are usually due to causes other than occasional constipation and that the article was not a treatment for such conditions when due to such other causes; (3) in that the statements, "Contains: Nux-Vomica 1.8 min. to ounce. Belladonna .45 min. to

ounce Herbs—including Senna, Buchu, Juniper Berries, Rhubarb, Jalap; Magnesium Sulphate, Cascara, & Iron (Ferric Chloride)," were misleading since they failed to reveal the fact that the physiological effects of the article were due essentially to its content of Epsom salt (magnesium sulfate), senna, and cascara sagrada; (4) in that the label failed to bear the common or usual name of each active ingredient, since magnesium sulfate is not the common or usual name of Epsom salt; and (5) in that its label failed to bear the name and quantities or proportions of strychnine, atropine, hyoscine, and hyoscyamine that were present.

On March 28, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

715. Misbranding of Starr's Wonderful M. L. & K. Pills. U. S. v. Fred Marion Starr (Starr Medicine Co.). Plea of nolo contendere. Fine, $100. (F. D. C. No. 6415. Sample No. 30265–E.)

The labeling of this product, in addition to failure to bear adequate warning statements, contained false and misleading claims and failed to bear the required ingredient and accurate quantity of contents statements.

On March 24, 1942, the United States attorney for the Northern District of California filed an information against Fred Marion Starr, trading as the Starr Medicine Co. at San Francisco, Calif., alleging shipment on or about February 18, 1941, from the State of California into the State of Illinois of a quantity of the above-named product that was misbranded.

Analysis of a sample of the article showed that it consisted essentially of extracts of plant drugs, including a laxative drug, coated with calcium carbonate.

It was alleged to be misbranded: (1) In that its labeling failed to bear adequate warnings against use in those pathological conditions where its use might be dangerous to health, or against unsafe dosage or methods or duration of administration, in such manner and form as are necessary for the protection of users, since it was a cathartic or laxative drug, and the labeling failed to bear a warning that it should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis are present, and that frequent or continued use might result in dependence on laxatives. (2) In that statements on the label, representing that it would be efficacious in the treatment of weak back, liver and kidney complaints, biliousness, fever, headaches, and indigestion were false and misleading since it would not be efficacious for such purposes. (3) In that it was fabricated from two or more ingredients and its label did not bear a statement of the common or usual name of each active ingredient. (4) In that it was in package form and did not bear a label containing an accurate statement of the quantity of contents in terms of numerical count.

On April 6, 1942, the defendant entered a plea of nolo contendere and the court imposed a fine of $100.

716. Misbranding of Weltone. U. S. v. 4 Cartons of Weltone and Accompanying Circulars. Default decree of condemnation and destruction. (F. D. C. No. 6792. Sample No. 70631–E.)

The labeling of this product failed to bear adequate directions for use and also bore false and misleading curative and therapeutic claims.

On January 31, 1942, the United States attorney for the Middle District of North Carolina filed a libel against 4 cartons (144 bottles) of Weltone and accompanying circulars, alleging that the article had been shipped in interstate commerce on or about January 10, 1942, by Standard Chemical, Inc., from Brooklyn, N. Y.; and charging that it was misbranded.

Analysis showed that the article consisted of a water solution of Epsom salt (28 percent) with inconsequential amounts of other salts, flavored with cassia and clove oils and sweetened with saccharin.

The article was alleged to be misbranded in that its labeling failed to bear adequate directions for use, since the following directions "Adults, about one to two tablespoonfuls twice daily in water before meals. Children (7 years or older): One teaspoonful in water before meals," provided for continued use, which might result in dependence upon laxatives. (2) In that the syllable "tone" forming a part of its name and the statements in an accompanying circular which represented that it would increase the appetite, prevent or cure headaches or run-down feeling, establish regularity in elimination, correct sluggish digestion, remedy incomplete elimination or sour stomach, prevent weakening run-down feeling due to constipation; that a periodic dose would

always help one; that it would eliminate any danger to general health or assist in digestive processes, would help one to feel his best, would not cause shock or strain or weakening aftereffects and would be good for every member of the family; and that unusual benefits would be derived from its use, were false and misleading since it possessed no tonic properties but was merely a laxative; it would not accomplish the results claimed, it might cause shock, strain, and weakening aftereffects; it would not necessarily be good for every member of the family; and there was nothing unusual about any benefits it might give. (3) In that the statement "Weltone Laxative is labeled in compliance with the Federal Food, Drug and Cosmetic Act" was false and misleading.

On April 17, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO COMPLY WITH OFFICIAL OR OWN STANDARDS

717. Adulteration and misbranding of Endocrine Extract Formula Nos. 2, 131, and 157; misbranding of Colloidal Dextro Calcium Bleything. U. S. v. The Bleything Laboratories. Plea of guilty. Fine, $520. (F. D. C. No. 4150. Sample Nos. 44102–E, 44425–E, 65833–E to 65835–E, incl.)

This case involved three shipments of endocrine extracts that were deficient in potency, and one of colloidal dextro calcium that contained a smaller amount of calcium than that indicated and implied in the labeling.

On April 28, 1942, the United States attorney for the Southern District of California filed an information against the Bleything Laboratories, a corporation at Los Angeles, Calif., alleging shipment within the period from on or about October 17, 1940, to on or about July 2, 1941, from the State of California into the State of Colorado of quantities of endocrine extracts that were adulterated and misbranded, and of colloidal dextro calcium that was misbranded.

Endocrine Extract Formula No. 2 was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and was represented to possess since it was represented to contain in each 33 cc., 3 milligrams of the crystalline principle of thyroid and 20 milligrams of the crystalline principle of entire ovary; whereas it contained no detectable amount of the crystalline principle of thyroid or of entire ovary. It was alleged to be misbranded in that the statements in the labeling, "Endocrine Extract * * * For Sublingual Use * * * Extracted principles of glands from government inspected animals and distilled water. * * * Extracted Crystalline Principles of the following glands: Thyroid . . . 3 mgm. * * * Entire Ovary . . . 20 mgm.," were false and misleading.

Formula No. 131 was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and was represented to possess since it was represented to contain in each 33 cc., 3 milligrams of the crystalline principle of thyroid and 10 milligrams of the crystalline principle of the male orchic gland; whereas it contained no detectable amount of the crystalline principle of the thyroid or of the male orchic gland. It was alleged to be misbranded in that the statements in the labeling, "Endocrine Extract * * * For Sublingual Use * * * Extracted principles of glands from government inspected animals and distilled water. * * * Extracted Crystalline Principles of the following glands: Thyroid . . . 3 mgm. * * * Male Orchic . . . 10 mgm.," were false and misleading.

Formula No. 157 was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and was represented to possess, since it was represented to contain in each 33 cc., 3 milligrams of the crystalline principle of thyroid, 10 milligrams of the crystalline principle of the pineal gland, and 5 milligrams of the crystalline principle of the male orchic gland; whereas it contained no detectable amounts of the crystalline principles of the thyroid, pineal, or male orchic glands. It was alleged to be misbranded in that the statements in the labeling, "Endocrine Extract * * * For Sublingual Use * * * Extracted principles of glands from government inspected animals and distilled water. * * * Extracted Crystalline Principles of the following glands: Thyroid . . . 3 mgm. Pineal . . . 10 mgm. * * * Male Orchic . . . 5 mgm.," were false and misleading.

The colloidal dextro calcium was alleged to be misbranded; (1) In that the statements, (bottle label) "Colloidal Dextro Calcium Bleything * * * Dosage: One teaspoonful three times daily before meals. May be taken in milk or

fruit juices, if preferred. In pronounced cases dosage may be doubled for two weeks. Dosage for children is the same as for adults," were false and misleading since they represented and suggested that in the dosages recommended, it would supply the user with sufficient calcium to be of therapeutic value in cases of ordinary calcium deficiency and even in cases of pronounced calcium deficiency; whereas in the maximum daily dosage recommended, namely, 6 teaspoonfuls, it would supply not more than $\frac{1}{750}$ of the amount of calcium required daily by an adult human being, which would be inconsequential for therapeutic purposes. (2) In that the statement on the label, "1-20 of 1% Sodium Benzoate," was false and misleading since it represented that the article contained not more than $\frac{1}{20}$ of 1 percent of sodium benzoate; whereas the two shipments of the product contained $\frac{1}{4}$ and $\frac{1}{5}$ of 1 percent, respectively, of sodium benzoate.

On May 21, 1942, a plea of guilty having been entered on behalf of the defendant, the court imposed a fine of $65 on each of the 8 counts of the information, totaling $520.

718. Adulteration and misbranding of elixir iron, quinine, and strychnine. U. S. v. Richard G. Dunwody (R. G. Dunwody & Sons, Inc.). Plea of guilty. Fine, $200. (F. D. C. No. 6455. Sample No. 48135–E.)

This product contained smaller amounts of tincture of iron citrochloride and quinine sulfate per fluid ounce than those declared on the label.

On May 1, 1942, the United States attorney for the Northern District of Georgia filed an information against Richard G. Dunwody, trading as R. G. Dunwody & Sons, Inc., at Atlanta, Ga., alleging shipment on or about April 14, 1941, from the State of Georgia into the State of Florida of a quantity of elixir iron, quinine, and strychnine which was adulterated and misbranded. It was labeled in part: "Tincture of Ferric Citrochloride 60 Minims Quinine Sulphate 4 grains."

The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and was represented to possess, since the label represented that it contained not less than 60 minims of tincture of ferric citrochloride and 4 grains of quinine sulfate per fluid ounce; whereas it contained not more than 23.8 minims of tincture of ferric citrochloride and not more than 3.08 grains of quinine sulfate per fluid ounce. It was alleged to be misbranded in that the statements in the labeling which represented that it contained 60 minims of tincture of ferric citrochloride and 4 grains of quinine sulfate per fluid ounce were false and misleading.

On May 9, 1942, the defendant entered a plea of guilty; and on May 29, 1942, the court imposed a fine of $200.

719. Adulteration of Estromone. U. S. v. Endo Products, Inc. Plea of guilty. Fine, $250. (F. D. C. No. 2967. Sample Nos. 20916–E, 24259–E, 28450–E, 34073–E, 46129–E to 46131–E, incl., 46133–E, 46134–E, 86212–E.)

On February 20, 1942, the United States attorney for the Eastern District of New York filed an information against Endo Products, Inc., Richmond Hill, N. Y., alleging shipment within the period from on or about December 28, 1939, to on or about November 20, 1940, from the State of New York into the States of North Carolina, Pennsylvania, Maryland, and New Jersey of quantities of Estromone which was adulterated.

The article was alleged to be adulterated in that its strength differed from or its quality fell below that which it purported or was represented to possess since (1) six of the shipments consisted of tablets which were represented to possess a biological activity equivalent to that of 2,000 International Units of estrogenic hormone; whereas the tablets in five shipments were found to possess a biological activity equivalent to that of not more than 600 International Units of estrogenic hormone and those in the sixth shipment possessed a biological activity equivalent to that of not more than 900 International Units per tablet. (2) One shipment consisted of tablets which were represented to possess a biological activity equivalent to that of 4,000 International Units of estrogenic hormone per tablet; whereas they possessed a biological activity equivalent to that of not more than 1,800 International Units of estrogenic hormone. (3) The remaining shipments were represented to consist of estrogenic substances in oil possessing in each cubic centimeter a biological activity equivalent to that of 5,000, 10,000, and 2,000 International Units, respectively, of estrogenic substance; whereas they possessed a biological activity equivalent to the activity of not more than 1,990, 1,740, and 1,325 International Units, respectively, of estrogenic substance.

On April 29, 1942, a plea of guilty was entered on behalf of defendant and the court imposed a fine of $250.

720. Adulteration and misbranding of hydrogen peroxide; misbranding of isopropyl alcohol, mineral oil, soda, and olive oil. U. S. v. Raymond Thomason and Clyde Rutledge (Southwest Products Co.). Pleas of guilty. Fines, $200. (F. D. C. No. 5565. Sample Nos. 6982–E, 6987–E, 6988–E, 6995–E, 65397–E, 65398–E.)

This case involved hydrogen peroxide which failed to conform to the pharmacopoeial specifications; mineral oil and soda the labeling of which bore false and misleading curative claims; and mineral oil, isopropyl alcohol, and olive oil which were short of the declared volume. The labeling of the soda also failed to bear adequate directions for use.

On March 2, 1942, the United States attorney for the Northern District of Texas filed an information against Raymond Thomason and Clyde Rutledge, trading as Southwest Products Co. at Lubbock, Tex., alleging shipment within the period from on or about September 16 to on or about November 22, 1940, from the State of Texas into the State of New Mexico of quantities of the above-named drugs which were adulterated and/or misbranded.

The hydrogen peroxide was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia but its strength differed from and its quality fell below the standard set forth therein, since in each 100 cubic centimeters it contained less than 2.5 grams of hydrogen peroxide (H_2O_2), namely, not more than 1.90 grams of hydrogen peroxide; whereas the United States Pharmacopoeia specifies that hydrogen peroxide shall contain in each 100 cc. not less than 2.5 grams of H_2O_2, and its difference in strength and quality from such standard was not plainly stated on the label. It was alleged to be misbranded in that the statement on the bottle label, "Hydrogen Peroxide U. S. P. * * * 3% * * * Active Ingredients H_2O_2 3%," was false and misleading since it represented that the article complied with the specifications of the United States Pharmacopoeia for solution of hydrogen peroxide and contained 3 percent of hydrogen peroxide; whereas it did not comply with such specifications and it contained not more than 1.9 percent of hydrogen peroxide.

One shipment of mineral oil was alleged to be misbranded in that the statement on the bottle label, "This oil is used for the treatment of chronic constipation and * * * for the relief of intestinal indigestion," was false and misleading since it represented and suggested that the oil would be efficacious for the treatment of chronic constipation and for the relief of intestinal indigestion; whereas it would not be efficacious for such purposes. The other shipment of mineral oil was alleged to be misbranded in that the statement on the bottle label, "Contents 1 Pint," was false and misleading since the bottles contained less than 1 pint, namely, amounts varying from 14.2 to 15.38 fluid ounces.

The soda was alleged to be misbranded: (1) In that the statement, (display cards) "For Relief of Indigestion, Heartburn, Acid Stomach, Common Colds," was false and misleading since it represented and suggested that soda was an efficacious treatment for indigestion, heartburn, acid stomach, and common colds; whereas it would not be efficacious for such purposes. (2) In that its labeling failed to bear adequate directions for use. (3) In that it was in package form and the package, i. e., envelope, did not bear a label containing the name and place of business of the manufacturer, packer, or distributor. (4) In that it did not bear a label containing its common or usual name, i. e., sodium bicarbonate.

The olive oil was alleged to be misbranded in that the statement on the bottle label, "1½ Fl. Oz.," was false and misleading since the bottles contained less than 1½ fluid ounces of olive oil, namely, amounts varying from 1.39 to 1.48 fluid ounces.

The isopropyl alcohol was alleged to be misbranded in that the statement on the bottle label. "Contents 1 Pint," was false and misleading since the bottles contained less than 1 pint of the article, namely, amounts varying from 15.2 to 15.85 fluid ounces.

The soda, one shipment of the mineral oil, the isopropyl alcohol, and the olive oil were alleged to be misbranded further in that they were in package form and did not bear labels containing accurate statements of the quantity of the contents.

On April 18, 1942, pleas of guilty were entered by the defendants and the court imposed a fine of $100 against each.

721. Adulteration of Antiseptic Medicated Skin Cream. U. S. v. 28 Jars of Antiseptic Medicated Skin Cream. Default decree of condemnation and destruction. (F. D. C. No. 7323. Sample No. 64944–E.)

On April 10, 1942, the United States attorney for the Western District of New York filed a libel against the above-named product at Buffalo, N. Y., alleging that

it had been shipped in interstate commerce on or about February 25 and March 12, 1942, by I. L. Palmer from Philadelphia, Pa.; and charging that it was adulterated in that its strength differed from that which it purported and was represented to possess, namely "Antiseptic."

On May 11, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

722. Adulteration and misbranding of citrate of magnesia. U. S. v. 36½ Dozen Bottles of Citrate of Magnesia. Default decree of condemnation and destruction. (F. D. C. No. 7189. Sample No. 64840–E.)

This product contained a smaller amount of magnesium citrate than that specified in the United States Pharmacopeia and it also contained sulfates in excess of the amount permitted in the pharmacopoeial product.

On April 11, 1942, the United States attorney for the Northern District of Ohio filed a libel against 36½ dozen bottles of citrate of magnesia at Youngstown, Ohio, alleging that the article had been shipped in interstate commerce on or about February 9, 1942, by the William Bettles Co. from Pittsburgh, Pa.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that it purported to be a drug the name of which is recognized in the United States Pharmacopoeia but its strength differed from and its quality fell below the standard set forth therein. It was alleged to be misbranded in that the statement "made of pure citric acid and carbonate of magnesia according to the U. S. Pharmacopoeia" was false and misleading since it was not correct.

On May 11, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

723. Adulteration and misbranding of Russian mineral oil. U. S. v. 477 Bottles, 113 Dozen Bottles, 487 Dozen Bottles, and 17 Drums of Russian Mineral Oil. Consent decree of condemnation. Product ordered released under bond to be relabeled. (F. D. C. No. 4817. Sample Nos. 56027–E, 56054–E.)

This product had been shipped in interstate commerce in drums and had been in part bottled and labeled by the consignee.

On or about May 26, 1941, the United States attorney for the District of Connecticut filed a libel against the above-named product at Bridgeport, Conn., in possession of McKesson & Robbins, Inc., alleging that it had been shipped on or about May 2 and 3, 1940, by Kuhne-Libby Co. from New York, N. Y.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, i. e., white mineral oil, but its quality fell below the standard set forth in the pharmacopoeia with respect to viscosity, and the difference in quality from such standard was not plainly stated on the label since the designation appearing on the bottles, "Light Russian Mineral Oil" and that on the drums, "Russian Mineral Oil U. S. P. Light," did not serve to warn the purchaser that it was not white mineral oil as that term is defined in the pharmacopoeia.

It was alleged to be misbranded in that the designation "light" (in comparatively small type) and "Russian Mineral Oil" (in comparatively large type) on the bottle labels, and the designation "Russian Mineral Oil U. S. P. Light" on the drums, were misleading since the term "Russian Mineral Oil" is associated in the minds of purchasers with an oil having a kinematic viscosity which is substantially higher than that of said article.

On April 9, 1942, McKesson & Robbins, Inc., New York, N. Y., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond to be relabeled under the supervision of the Food and Drug Administration.

724. Adulteration and misbranding of vitamin tablets. U. S. v. 27,500 Vitamin A and D Tablets. Default decree of condemnation and destruction. (F. D. C. No. 7054. Sample No. 30494–E.)

This product was represented to contain 625 units of vitamin D per tablet but contained not more than 470 units of vitamin D per tablet.

On March 18, 1942, the United States attorney for the Eastern District of Michigan filed a libel against 27,500 vitamin tablets at Detroit, Mich., alleging that the article had been shipped in interstate commerce on or about January 5, 1942, by Strong, Cobb & Co., Inc., from Cleveland, Ohio; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that its strength differed from and its quality fell below that shown on the label, 625 units [of vitamin D] per tablet.

It was alleged to be misbranded in that statements on the label pertaining to vitamin D content, "Active Ingredients Only—Per Tablet Vitamin D (Viosterol) 625 Units Each Tablet Contains The Equivalent of Two Teaspoonsfulls Cod Liver Oil Minimum USP Strength in Vitamin Potency," were false when applied to an article that contained not more than 470 U. S. P. units of vitamin D per tablet.

The article was also charged to be adulterated and misbranded in violation of the provisions of the law applicable to food, as reported in F. N. J. No. 3643.

On May 5, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING STATEMENTS IN THE LABELING[2]

725. Action to enjoin and restrain distribution in interstate commerce of Diaplex under false and misleading labeling. U. S. v. Henry Wayne Pierce (Horace Wayne Pierce) and Alice Pierce. Permanent injunction granted. (Inj. No. 18.)

On October 14, 1941, the United States attorney for the District of Colorado filed a complaint against Henry Wayne Pierce, also known as Horace Wayne Pierce, and Alice Pierce, Larimer, Colo., alleging that the defendants were engaged in the business of selling, distributing, and shipping in interstate commerce, and on numerous occasions had shipped or caused to be shipped to various persons throughout the United States a food, drug, or weed commonly known as Diaplex, which bore certain false and misleading statements in the labeling as quoted hereinafter.

The complaint alleged further that the defendant on divers occasions had been informed that the statements on the labels hereinafter quoted were false and misleading and that said product was misbranded; that the defendants had been warned that further shipments in interstate commerce of Diaplex with false and misleading statements on the labels must cease; that the defendants had continued to ship and cause to be shipped in interstate commerce large quantities of Diaplex with directions and false and misleading statements printed on the labels; that they had announced their present and future intentions to continue making shipments of Diaplex in interstate commerce with the said false and misleading statements in the labeling until restrained and enjoined by law from doing so; and prayed that a temporary injunction issue restraining the defendants and those acting on their behalf from shipping such product or causing it to be shipped in interstate commerce and that the temporary injunction be made permanent on final hearing of the case.

On October 29, 1941, the court orally instructed the defendants that neither they nor their agents were to conduct any further business in the manufacture and interstate shipment of the article, pending the hearing of medical testimony on November 22, 1941.

On October 31, 1941, the defendants filed an answer denying the making of any dogmatic claims of cure for the product and also denying that the labeling was false and misleading. On December 1, 1941, the case having come on for trial and the plaintiffs having appeared by counsel and the defendants appearing for themselves and without counsel, the court made the following findings of fact and conclusions of law:

I

SYMES, *D. J.* "That at all times hereinafter mentioned, and for a long time prior thereto, the defendants, Henry Wayne Pierce, also known as Horace Wayne Pierce, and Alice Pierce, were engaged in the business of selling, distributing, and shipping in interstate commerce, a product more commonly known as 'Diaplex' for the treatment and benefit of persons suffering from diabetes.

II

"That on or about July 3, 1941, the defendants did ship and cause to be shipped in interstate commerce, namely, from the town of Wellington, Colo., a shipment of a product more commonly known as 'Diaplex' and billed as 'dried

[2] See also Nos. 701–706, 708, 710, 711, 714–717, 720.

herbs ground,' to Henry Legler at Boise, Idaho; that said shipment consisted of 5 boxes, each box containing 50 cartons of the product known as Diaplex; that each carton had then and there affixed the following label: 'Diaplex—Directions as a Beverage: Place two heaping tablespoons of Diaplex in a porcelain or earthen percolator (never use aluminum) and pour one quart of hot water over it, percolate same for ten minutes and serve hot. Directions to Doctors: For those whose blood-sugar count tests 125 Mgs. per 100 C.C. or over, use four heaping tablespoons of Diaplex to the quart of water and percolate ten to fifteen minutes. Always serve Diaplex hot, never ice cold or lukewarm. (Never use aluminum.) An adult should use two quarts of Diaplex tea daily and a child, one, for a period of nine to eighteen months. Diaplex is a food, not a drug. It should never lower the blood-sugar below normal. Therefore, a great amount is effective. Small doses are worthless for the diabetic. Diaplex contains no opiates and is non-injurious. Notice! . . . Warning! Persons using Diaplex with insulin should make the urine test daily, and as the pancreas increases its normal function, reduce the amount of insulin sufficiently to avoid insulin reaction. Only use enough insulin to take care of the surplus sugar reducing the amount of insulin from time to time sufficiently to avoid insulin reaction; but continue the use of Diaplex until you are well and strong. If you are using Protamine Zinc insulin write for further instructions; Diaplex, Wellington, Colorado Diaplex—Trademark reg. U. S. Pat Office—by H. W. Pierce. Net Weight 12 ounces avoirdupois when packed.'

III

"That the defendants were on this and previous occasions informed by proper notice, through the proper officials and representatives of the plaintiff, that the statements printed on said label in conjunction with the name 'Diaplex' were false and misleading when the product was presented either as a food or as a drug.

IV

"That the defendants did on September 22, 1941, notify the plaintiff, through its proper officials and representatives that they produced Diaplex and would continue to sell it in interstate commerce.

V

"That said product more commonly known as 'Diaplex' has never been recognized as a food for human consumption, nor is it a plant containing ingredients of medicinal value, but on the contrary, is a common weed, saltbush, which is scientifically known as *Atriplex canescens.*

Conclusions of Law

I

"That the product commonly known as 'Diaplex,' as heretofore described in the complaint and as so labeled, is misbranded in violation of the Federal Food, Drug, and Cosmetic Act, a statute 'to prohibit the movement in interstate commerce of adulterated and misbranded food, drugs, devices and cosmetics, and for other purposes,' by reason of the false and misleading statements directly and impliedly indicating that the product was and is of therapeutic value in the treatment of diabetes.

II

"That the plaintiff is entitled to a permanent injunction enjoining said defendants, their agents, servants, employees, attorneys, representatives, and assigns, and all persons acting or claiming to act in their behalf in the same regard and the same effect from shipping or causing to be shipped in interstate commerce, or from receiving in interstate commerce, shipments of the weed, saltbush (*Atriplex canescens*) for subsequent sale under the name 'Diaplex,' or other language directly and impliedly offering or claiming the product of therapeutic value in the treatment of diabetes."

On December 5, 1941, a decree was entered granting a permanent injunction in accordance with the prayer of the complaint.

726. Action to enjoin and restrain distribution of Slend-R-Form, a misbranded candy. U. S. v. Riley Products, Inc., and George C. Riley. Judgment ordering permanent injunction. (Inj. No. 15.)

On February 2, 1942, the United States attorney for the Northern District of Illinois filed a complaint against Riley Products, Inc., a corporation, and George C. Riley, an officer of said corporation, alleging that the defendants for several months past, and more particularly on or about October 28, 1940, had been introducing and delivering for introduction in interstate commerce, a product consisting of a drug and a food, labeled in part "Slend-R-Form the New Candy," alleging that in form and appearance it was like ordinary caramel candy, that it was packed, distributed, and sold by the defendants in cardboard cartons which cartons and smaller cartons contained therein and the accompanying circulars had printed thereon statements referring to its efficacy and the quantity to be consumed.

The complaint alleged further that the labeling of the article was false and misleading since it created the impression in the minds of the purchaser that it was a reducing agent and that when consumed in the manner and in the quantity recommended in the labeling it would be of substantial value in reducing body weight, whereas it contained no ingredients or combination of ingredients capable of producing the effects claimed for it as a reducing agent when consumed in accordance with the directions contained in the labeling.

The complaint alleged further that the defendants, unless restrained by the court, would continue to introduce and deliver for introduction in interstate commerce the said article or a similar article of drug or food misbranded in the manner aforesaid, and prayed that they be permanently enjoined and restrained from doing so and further prayed that a temporary restraining order and preliminary injunction issue. On the same date, the United States attorney filed a motion for an order to show cause why the defendants should not be enjoined and restrained during pendency of the action.

On February 6, 1942, the court entered a preliminary injunction against the defendants pursuant to the prayer contained in the complaint.

On April 10, 1942, the cause having been called for a hearing, judgment was entered permanently enjoining and restraining Riley Products, Inc., and George C. Riley, their agents, employees, and representatives and all others acting by or under their direction or authority or in active concert or participation with them from introducing or delivering for introduction in interstate commerce, the product labeled in part "Slend-R-Form, the New Candy" or a similar article of drug or food similarly labeled. It was provided further that the United States of America recover the costs of the action.

727. Misbranding of Bronchi-Lyptus. U. S. v. Mrs. Millie R. Binz, Mrs. Maude F. Boynton, and Ralph H. Boynton (Bronchi-Lyptus Laboratory). Pleas of nolo contendere. Imposition of sentences suspended and defendants placed on probation for 1 year. (F. D. C. No. 5489. Sample No. 32653–E.)

On October 27, 1941, the United States attorney for the Southern District of California filed an information against Mrs. Millie R. Binz, Mrs. Maude F. Boynton, and Ralph H. Boynton, copartners trading as Bronchi-Lyptus Laboratory at Los Angeles, Calif., alleging shipment on or about September 3, 1940, from the State of California into the State of Arizona of a number of packages, each containing a number of bottles enclosed in cartons, and a number of sample vials, of Bronchi-Lyptus which was misbranded.

Analyses of samples of the product showed that it consisted essentially of oil of eucalyptus, a gum, glycerin, sugar, and water.

The article was alleged to be misbranded in that the name "Bronchi-Lyptus," and certain statements in the labeling which represented and suggested that the article was efficacious in the treatment of affections of the bronchi, would relieve inflamed tissues and soothe the mucous membrane, would be efficacious in the treatment of all throat irritations, would relieve night attacks of spasmodic croup or coughing almost immediately; that it was a treatment accepted by all nose and throat specialists and was highly efficacious in assisting the delicate organs of the throat to throw off conditions that might lead to serious affections, would assist nature in its efforts to bring about recovery from coughs and colds, would provide relief in chronic conditions of the throat or lungs, and would aid one in recovering from such conditions; and that it would correct fermentation in the stomach, were false and misleading since it would not be efficacious for such purposes. The article contained in the sample vial was alleged to be misbranded further in that its label did not bear an accurate statement of the quantity of the contents.

On November 30, 1941, the defendants were arraigned and entered pleas of not guilty. On April 21, 1942, the defendants moved for an order requiring greater particularity in certain respects, particularly whether the Government intended to introduce evidence that the word "Bronchi-Lyptus" constituted misbranding, in what respect this word violated the law, and in what respect persons reading the article would be led to believe that it was a competent treatment for all chronic conditions of bronchial and nasal passages. On May 4, 1942, the defendants' motion for a bill of particulars came before the court and the court denied the motion announcing as grounds for such denial, first, that the name "Bronchi-Lyptus" was not misleading and; second, that assuming that it might have been misleading, the information contained no direct averment as to how or in what manner the name could be misleading. Thereupon the defendants changed their pleas of not guilty to pleas of nolo contendere, and the court ordered that the imposition of sentences be suspended and that the defendants be placed on probation for 1 year.

728. Misbranding of Gid Granules. U. S. v. Eberly-Williams Manufacturing Co. and Lawrence M. Williams. Pleas of guilty. Fine, $250 and costs. (F. D. C. No. 5534. Sample Nos. 36782–E, 36783–E.)

The labeling of a portion of Gid Granules No. 1 (in sample enevelopes) failed to bear adequate directions for use and was objectionable in other respects as indicated hereinafter. That of the remainder, in addition to bearing false and misleading curative claims, falsely represented that it was not a laxative drug.

On February 27, 1942, the United States attorney for the Northern District of Illinois filed an information against the Eberly-Williams Manufacturing Co., a corporation, Chicago, Ill., and Lawrence M. Williams, alleging shipment within the period from on or about April 9 to on or about April 17, 1941, from the State of Illinois into the State of Massachusetts of quantities of Gid Granules No. 1 and Gid Granules No. 2, and a number of sample envelopes containing Gid Granules No. 1, which were misbranded.

Analyses showed that Gid Granules No. 1 consisted essentially of the mucilaginous portion of psyllium seed, karaya gum, sodium bicarbonate, calcium carbonate, and sugar; and that Gid Granules No. 2 consisted essentially of the mucilaginous portion of psyllium seed, karaya gum, yeast, and sugar.

Both articles were alleged to be misbranded in that the statements on the packages and cartons, (No. 1) "are scientifically prepared to be of effective value in the treatment of minor irritations and inflammations of the stomach and upper intestines" and (No. 2) "are scientifically prepared to be of effective value in the treatment of minor irritations and inflammations of the lower intestine and colon, and in spastic * * * constipation," and those in an accompanying circular, were false and misleading since they represented that the articles would be efficacious in the treatment of minor irritations and inflammations of the lower intestine and colon and in spastic constipation; that they were appropriate and effective treatments for stomach troubles, intestinal disorders, indigestion, diarrhea, sore stomach, bad breath, gnawing pains, gas pains, dyspepsia, biliousness, headaches, sleeplessness, intestinal stasis, auto-intoxication, colitis, colonic irritation, liver and gall deficiencies (not due to infection), intestinal trouble, lesions, stasis, toxemia, putrefaction, flatulence, stomach ulcer, or tuberculosis or cancer of the gastric tract, sore and lacerated ulcers of the upper parts of the gastric tract, the stomach, duodenum, jejunum, small intestine, troubles located in the lower intestines, cecum, ascending and transverse colon, sigmoid, and rectum; whereas they would not be efficacious for such purposes.

They were alleged to be misbranded further in that the statements "Gid, a mucinoid from cereal * * * it is significant that Gid supplies elements that Nature intended to be in man's natural food, but which have been largely lost in the refinement of food processing, Gid is for that reason essentially a food supplement. Certainly it is not a drug or a medicine in the ordinary sense of the word, * * * this * * * food supplement. Gid is not a laxative or cathartic. It has little or no such action. Its help is altogether different. Those who have had to depend on drug or oil laxatives will find Gid a delightful comfort," appearing in the labeling, were false and misleading since the articles were not prepared from a cereal, would not supply elements that nature intended to be in man's natural food but which had been largely lost in the refinement of food processing, they were not food supplements but were drugs in the ordinary sense of the word, and were laxative or cathartic drugs.

The article contained in the sample envelopes was alleged to be misbranded further (1) in that it was in package form and did not bear a label containing

the name and place of business of the manufacturer, packer, or distributor, nor a statement of the quantity of the contents; (2) in that it was fabricated from two or more ingredients and its label did not bear the common or usual name of each active ingredient; and (3) in that its labeling did not bear adequate directions for use, since the envelopes bore no directions at all.

On March 3, 1942, pleas of guilty having been entered on behalf of the defendants, the court imposed a fine of $250 and costs, which was applicable to both defendants.

729. Misbranding of Merlek Mineral Water. U. S. v. Michael Lee (Lee Bros.). Plea of nolo contendere. Fine, $1,000. Defendant placed on probation for 5 years. (F. D. C. No. 5527. Sample No. 7399–E.)

This product consisted of sea water to which had been added a small amount of potassium iodide. Its labeling bore false and misleading claims regarding its mineral content and its efficacy in conditions of impaired health resulting from mineral deficiency.

On January 3, 1942, the United States attorney for the Northern District of California filed an information against Michael Lee, trading as Lee Bros., Oakland, Calif., alleging shipment on or about May 18, 1940, from the State of California into the State of Arizona of a quantity of Merlek which was misbranded.

The article was alleged to be misbranded in that the statements, "Contains Parts Per Million (Approximate Analysis) Sodium & Potassium Chlorides: 28924.7 Magnesium Chloride: 3286.9 Magnesium Sulphate: 3106.7 Calcium Sulphate: 857.3 Calcium Chloride: 573.0 * * * Magnesium Bromide: 76.0 Alkaline Nitrates: 42.5 Traces of Phosphorus, Boron, Silica, Sodium Fluoride, Iron Oxide, Aluminum Oxide * * * Merlek is sold only to help supply minerals for mineral deficiency," borne on the label, were false and misleading since they represented and suggested that it contained the above-named minerals in amounts sufficient to contribute in an important respect to the requirements of the body for such minerals, and that it would be efficacious in conditions of impaired health resulting from deficiency of said minerals; whereas it would not contribute in an important respect to the requirements of the body for such minerals since it contained inconsequential amounts of minerals and would not be efficacious in conditions of impaired health resulting from deficiency of such minerals. It was alleged to be misbranded further in that its labeling was misleading since it failed to reveal the fact, material in the light of the representations in the labeling, that it consisted of sea water to which had been added a small amount of potassium iodide.

The article was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in F. N. J. No. 3839.

On June 9, 1942, the defendant entered a plea of nolo contendere and the court imposed a fine of $1,000 and placed the defendant on probation for 5 years.

730. Misbranding of Hoyt's Compound. U. S. v. Herman P. Doyle, Verne N. Seeley, and Fred D. Grantham (Hoyt Chemical Co.). Pleas of guilty. Fines, $600. (F. D. C. No. 6462. Sample No. 52314–E.)

On May 11, 1942, the United States attorney for the District of Colorado filed an information against Herman P. Doyle, Verne N. Seeley, and Fred D. Grantham, trading as the Hoyt Chemical Co. at Denver, Colo., alleging shipment on or about May 27, 1941, from the State of Colorado into the State of Washington of a quantity of Hoyt's Compound that was misbranded.

Analysis of a sample of the article showed that it consisted essentially of extracts of plant drugs including a laxative drug, alcohol, and water.

It was alleged to be misbranded in that representations in the labeling that it would be efficacious in the treatment of indigestion, sour stomach, gas, bloating, nervousness, excitability, skin and blood diseases, stomach trouble, constipation, run-down condition, sleeplessness, belching and burning sensation in the throat and stomach, pains in the hips and legs, gas and pressure around the heart, dizziness, lump in the stomach, twitching, jerking, spots before the eyes, and knotty sensation in the stomach; that it would be efficacious to prevent suffering after meals and to quiet the nerves and restore health; that it would be efficacious in the relief of suffering from stomach, bowels, and kidneys; that it would be efficacious to prevent getting up nights caused by kidney affections, to produce gain in weight, to cleanse the bowels and leave the intestinal tract pure and clean and free of poisonous waste matter, and to make the bowels normal; that it would be efficacious in the treatment of all kinds of aches and pains and disorders of the general health; and that it was a wonderful treatment for poor health

and tired and run-down conditions; were false and misleading since it would not be efficacious for such purposes.

On May 15, 1942, the defendants entered pleas of guilty and the court fined each one $200.

731. Misbranding of Renair Pomade. U. S. v. Frederick Godfrey (Adams Products Co.). Plea of guilty. Fine, $300. (F. D. C. No. 4183. Sample No. 33157–E.)

The labeling of this product bore false and misleading representations regarding its efficacy as a treatment for baldness or thinning and falling hair.

On February 12, 1942, the United States attorney for the Northern District of New York filed an information against Frederick Godfrey, Adams, N. Y., alleging shipment, in the name of the Adams Products Co., on or about May 14, 1940, from the State of New York into the State of New Jersey of a quantity of Renair Pomade which was misbranded. The article was labeled in part as follows: (Jars) "Renair Pomade and Massage Stimulate the Scalp. * * * For Thinned Areas. * * * For Falling Hair."

Analysis showed that the article was an amber-colored ointment containing betanaphthol and volatile oils with cedar-like odor in small amount incorporated in a base consisting chiefly of petrolatum and a smaller amount of fatty material.

The article was alleged to be misbranded in that its labeling bore representations that, when used alone or in conjunction with certain pulling, massaging, and kneading treatments recommended in the labeling, it would produce beneficial effects in the treatment of baldness, falling hair, and thinned hair, whereas it would not produce the beneficial effects claimed for it in the labeling, whether used alone or in conjunction with such treatments.

On April 20, 1942, the defendant entered a plea of guilty and the court imposed a fine of $300.

732. Misbranding of Betene. U. S. v. 350 Cans and 130 Cans of Betene. Decree of condemnation. Product ordered released under bond to be relabeled. (F. D. C. No. 6877. Sample No. 64672–E.)

On February 16, 1942, the United States attorney for the Western District of Pennsylvania filed a libel (amended March 21, 1942) against 480 cans of Betene at Rochester, N. Y., alleging that the article had been shipped in interstate commerce on or about November 25, 1941, from Rochester, N. Y., by the L. H. Stewart Corporation; and charging that it was misbranded.

Analysis of a sample of the article showed that it consisted essentially of a mixture of dried skim milk, dried egg yolk, soya bean tissues, wheat bran, wheat germ, salt, agar agar, calcium phosphate, chondrus (Irish moss), and saccharin, flavored with cocoa, vanillin, and coumarin, together with certain added vitamin substances.

The article was alleged to be misbranded in that statements in the labeling which represented and suggested that when consumed as directed, it would cause an increase in weight, would give vigor and vitality to the user and that it constituted a sure, sane, safe, and effective way to reduce, were false and misleading since its use would not accomplish such results.

It also was alleged to be misbranded under the provisions of the law applicable to foods, as reported in F. N. J. No. 3840.

On May 21, 1942, the L. H. Stewart Corporation having appeared as claimant, and having admitted that the allegations of the libel were substantially correct, judgment of condemnation was entered and it was ordered that the product be released under bond conditioned that it be relabeled under the supervision of the Food and Drug Administration.

733. Misbranding of Camelline. U. S. v. 9 Dozen Bottles of Camelline. Default decree of condemnation and destruction. (F. D. C. No. 6948. Sample No. 63431–E.)

On March 7, 1942, the United States attorney for the District of Oregon filed a libel against the above-named product at Portland, Oreg., alleging that it had been shipped on or about August 28, 1941, by Walter M. Willett from San Francisco, Calif.; and charging that it was misbranded.

Analyses of samples of the article showed that it consisted essentially of calcium carbonate, bismuth, subcarbonate, alcohol, and water.

The article was alleged to be misbranded in that statements on the bottle label and in an accompanying circular suggesting and representing that it was efficacious in preventing tooth decay, freckles, sunburn, poison ivy, poison oak, and in relieving the irritation caused by poison oak and poison ivy, were false and misleading since it would not be efficacious for such purposes.

It was also alleged to be misbranded under the provisions of the law applicable to cosmetics, as reported in C. N. J. No. 85.

On April 13, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

734. Misbranding of Chek-A-Cold. U. S. v. 66 Packages and 69 Packages of Chek-A-Cold. Default decree of condemnation and destruction. (F. D. C. No. 7475. Sample No. 77023–E.)

On or about May 7, 1942, the United States attorney for the District of Delaware filed a libel against 135 packages of Chek-A-Cold at Newark, Del., alleging that the article had been shipped in interstate commerce on or about March 13, 1942, by Hance Bros. & White, Inc., from Philadelphia, Pa.; and charging that it was misbranded.

Examination of a sample of the article showed that it consisted essentially of extracts of plant drugs including an alkaloid-bearing drug, a small proportion of tartaric emetic, chloroform (0.97 minims per fluid ounce), alcohol, sugar, and water.

It was alleged to be misbranded in that the designation "Chek-A-Cold" and the statement "Each Fluid Ounce Contains: Chloroform . . . . . 4 minims," borne on the carton and bottle label, were false and misleading, since the article contained no ingredient capable of checking a cold and contained materially less than 4 minims of chloroform in each fluid ounce.

On May 27, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

735. Misbranding of Cook's Laxative Cold Breakers. U. S. v. 21 Dozen Packages of Cook's Laxative Cold Breakers. Default decree of condemnation and destruction. (F. D. C. No. 6306. Sample No. 59686–E.)

On or about November 28, 1941, the United States attorney for the Western District of Virginia filed a libel against the above-named product at Grundy, Va., alleging that the article had been shipped in interstate commerce on or about September 16, 1941, by the Thomas E. Cook Chemical Co. from Frederick, Md.; and charging that it was misbranded.

Analysis showed that the article contained acetophenetidin (approximately 1 grain per tablet), cinchonine sulfate (0.26 grain per tablet), camphor, aloin, podophyllin, and cayenne pepper.

The article was alleged to be misbranded in that statements in the labeling which represented that it was efficacious as a remedy for colds and the accompanying ailments, loss of appetite, etc., and that it would break colds, were false and misleading, since it would not be efficacious for such purposes. It was alleged to be misbranded further in that the statements in the labeling "They Contain No Quinine" and "if your druggist cannot supply you, * * * we will mail you a box direct from our laboratory," were false and misleading since the article contained cinchonine, a cinchona alkaloid having properties generally similar to those of quinine, which is also a cinchona alkaloid, and since the firm maintained no laboratory but merely repackaged medicines manufactured in other establishments.

On May 4, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

736. Misbranding of Gold Medal Compound Pills and Savatan. U. S. v. 9⅝ Dozen Packages of Gold Medal Compound Pills and 5½ Dozen Packages of Savatan. Default decree of condemnation and destruction. (F. D. C. Nos. 7099, 7100. Sample Nos. 72230–E, 72231–E.)

On March 27, 1942, the United States attorney for the Southern District of California filed a libel against the above-named drug products at Los Angeles, Calif., alleging that they had been shipped in interstate commerce on or about February 16, 1942, by the S. Pfeiffer Manufacturing Co. from St. Louis, Mo.; and charging that they were misbranded. They were labeled in part: "Gold Medal Compound Pills * * * Virginia Chemical Company, St. Louis, Mo." or "Savatan * * * S. Pfeiffer Manufacturing Co., St. Louis, Mo."

Analysis of a sample of the Gold Medal Compound Pills showed that they consisted essentially of iron sulfate and small amounts of volatile oils including oil of spearmint. Analysis of a sample of Savatan showed that each capsule contained approximately 5 minims of apiol.

The articles were alleged to be misbranded in that the following statements in the labeling were misleading since they represented and suggested

that they would be efficacious in relieving minor discomforts associated with menstruation; whereas they would not be efficacious for such purpose: (Gold Medal Compound Pills) "Directions. One pill before meals and at bedtime. Begin a day or two before expected period or when functional discomfort appears. At bedtime, a brief hot foot bath up to the knees or hot sitz bath is suggested to help improve local circulation, if needed. Drink a pint or less of hot ginger tea a few days before regular time. Keep feet and body warm and bowels open. * * * Intended only for palliative relief in minor discomforts, not as a remedy for diseases and underlying causes which might affect functional menstruation"; (Savatan) "Directions. Take one Savatan four times a day, before meals and at bedtime. It may be desirable to take a brief hot foot bath up to the knees or hit sitz bath to improve pelvic circulation. A few days before expected period or when functional discomfort appears, drink freely a pint if possible of hot ginger tea and keep the body warm. * * * Savatan is intended only for palliative relief and not as a remedy for diseases and underlying causes which might affect functional menstruation."

On April 22, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

737. Misbranding of Green's Reliable Restorer. U. S. v. 8¼ Dozen Bottles of Green's Reliable Restorer. Default decree of condemnation and destruction. (F. D. C. No. 7434. Sample No. 80742–E.)

The labeling of this product bore false and misleading claims that it would restore gray hair to its natural color and would be efficacious in the treatment of certain scalp conditions.

On May 2, 1942, the United States attorney for the Eastern District of Kentucky filed a libel against the above-named product at Grayson, Ky., alleging that it had been shipped in interstate commerce on or about February 16, 1942, by A. J. Green from Clarksburg, W. Va.; and charging that it was misbranded.

Analysis showed that the article consisted essentially of lead acetate, lead sulfate, sulfur, zinc acetate, alcohol, glycerin, oil of bay, and water.

The article was alleged to be misbranded in that the following statements in the labeling, "Contents: Sulphur, Zinc Sulfate, Acetate Merck, Glycerine, Bay Rum, Water Reliable Restorer * * * This preparation restores grey or faded hair to its natural color Frees the scalp from Dandruff and All Contagious Eruptions Stops hair from falling, promotes its growth * * * To Restore Growth—Apply the 'Restorer' daily and brush the scalp vigorously with a stiff brush," were false and misleading, since it contained no zinc sulfate but did contain lead salts which were not declared, and it would not restore the natural color to gray or faded hair, would not free the scalp from dandruff and all contagious eruptions, and would not restore the growth of hair or prevent it from falling. It was alleged to be misbranded further in that the label failed to bear an accurate statement of the quantity of the contents.

On May 25, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

738. Misbranding of O'Dara. U. S. v. 142 3-Fluid-Ounce Bottles of O'Dara. Default decree of condemnation and destruction. (F. D. C. No. 6186. Sample No. 73339–E.)

This product was not antiseptic when used in the dilutions recommended in the labeling, and the labeling also bore false and misleading therapeutic claims.

On January 6, 1942, the United States attorney for the District of Nebraska filed a libel against the above-named product at Omaha, Nebr., alleging that it had been shipped in interstate commerce from St. Louis, Mo., by O'Dara Products Co. on or about April 28, 1941; and charging that it was misbranded.

Analysis of a sample of the article showed that it consisted essentially of alcohol (46 percent), glycerin (17 percent), potassium iodide (5 percent), methyl salicylate (7 percent), zinc chloride (3 percent), phenol (1 percent), water, and small proportions of saccharin and myrrh. Bacteriological examination showed that it would not be antiseptic when used in the dilution of 1 teaspoonful to a glass of water.

The article was alleged to be misbranded: (1) In that statements in the labeling which represented that it constituted a proper or adequate treatment for pyorrhea, trench mouth, canker sores, stomatitis, or spongy gums; that it would coagulate, detach, and clear away objectionable matter, leave the tissues clean and have a healing effect or stimulate healing processes; that it would kill disease-producing organisms embedded in the tissues to which it was applied; that it was an

adequate treatment for sore throat; that it would act as a blood coagulant forming a protective film over wounds; and that it was an adequate treatment for painful erupting teeth and for painful conditions or severe swelling after extraction of teeth, were false and misleading since it would not be efficacious for such purposes, except that it might act as a blood coagulant and form a protective film over wounds of a minor character. (2) In that the following statements, (carton, bottle label, and circular) "Concentrated antiseptic in undiluted state. Astringent, Deodorant, Mouth Wash, Gum Massage and Gargle," (carton and bottle) "Directions: As a mouth wash or gargle use about a teaspoonful to glass of water or enough to give you a tingling feeling on tongue," and (circular) "Wash: as a mouth wash for daily use, use about a teaspoonful to a glass of water (you may use cap on bottle, which holds a teaspoonful) or use according to your taste, but enough to give your tongue a tingling feeling. * * * Gargle: For a sore throat, a teaspoonful to a glass of hot water every two hours * * * The contents of this 3 oz. bottle make a gallon and one-half of mouth wash when diluted," were false and misleading particularly in the absence of a statement in the labeling that it would not be antiseptic when used in some of the dilutions recommended, namely, "about a teaspoonful to a glass of water," and "The contents of this 3 oz. bottle makes a gallon and one-half of mouth wash when diluted," an omission material in the light of the prominent display of the words "Concentrated Antiseptic In Undiluted State. Astringent, Deodorant, Mouth Wash, Gum Massage and Gargle" on the carton, bottle label, and circular.

On February 18, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

739. Misbranding of Na-Stim. U. S. v. 6 Dozen Packages of Na-Stim A Nasal Stimulant. Default decree of condemnation and destruction. (F. D. C. No. 6895. Sample No. 72559–E.)

On February 21, 1942, the United States attorney for the District of Arizona filed a libel against 6 dozen packages of Na-Stim at Phoenix, Ariz., alleging that the article had been shipped in interstate commerce on or about November 24, 1941, by the Na-Stim Laboratories, Inc., from Modesto, Calif.; and charging that it was misbranded.

Analysis showed that the article consisted essentially of water, a gum, and fatty material; but failed to reveal the presence of menthol, oil of pine, or turpentine.

The article was alleged to be misbranded: (1) In that the statement on the tube labels "Contains * * * Menthol, Venice Turpentine, Oil of Pine, Iodine," was false and misleading since it contained no detectable amount of menthol, Venice turpentine, oil of pine, or free iodine, and contained merely a trace of combined iodine. (2) In that statements in the labeling which represented that it would be efficacious for the relief from symptoms of hay fever, sinus, head colds, and nasal disorders, and that it constituted an adequate treatment for such conditions, were false and misleading since it would not be efficacious for such purposes and was not an adequate treatment for such conditions.

On April 21, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

740. Misbranding of Omega Oil and Kotalko. U. S. v. 59½ Dozen Bottles of Omega Oil and 34 Packages of Kotalko. Default decrees of condemnation and destruction. (F. D. C. Nos. 6764, 7830. Sample Nos. 89107–E, 89880–E.)

The labeling of both products bore false and misleading therapeutic claims. The Kotalko ointment failed to bear the common or usual name of each of its active ingredients on the label, and the box in which it was packed occupied less than one-third of the capacity of the carton.

On February 10 and June 30, 1942, the United States attorney for the Southern District of New York filed libels against the above-named articles at New York, N. Y., alleging that they had been shipped in interstate commerce on or about December 22, 1941, and May 11 and June 2, 1942, by Block Drug Co., Inc., from Jersey City, N. J.; and charging that they were misbranded.

Analyses of samples of the articles showed that Omega Oil consisted essentially of chloroform, methyl salicylate, mineral oil, and a small quantity of alkaloidal material such as hyoscyamus; and that the Kotalko consisted essentially of sulfur, pilocarpine, resorcinol, and a camphoraceous oil in an ointment base.

The Omega Oil was alleged to be misbranded in that statements in the labeling which represented that it differed from ordinary liniments, that it was "far more than just liniment," that it was a powerful and reliable answer to dozens of everyday ills; that at the point of application it would soothe and ease the local nerves, stimulate the circulation, break up congestion

and thus quickly and directly relieve pain and its congestive cause; that it would relieve rheumatic pains due to exposure, dampness, and cold; that it would be helpful in the treatment of bruises, would help relieve suffering from varicose veins, would bring quick relief of athlete's foot, and toe itch, would relieve chest and throat colds, and tightness and congestion in throat and chest muscles, were false and misleading since it was a counter-irritant liniment and did not possess the properties claimed for it.

Kotalko was alleged to be misbranded: (1) In that representations in the labeling that it would discourage excessive loss of, and strengthen existing growth of, hair and aid in promoting new growth; and that it would be efficacious in the treatment of dandruff, thin, brittle or falling hair, and baldness, were false and misleading since it would not be efficacious for such purposes. (2) In that it was fabricated from two or more ingredients and its label failed to bear the common or usual name of each of the active ingredients. (3) In that its container was so filled as to be misleading since the retail carton was materially larger than necessary to hold the contents.

On April 20 and July 29, 1942, no claimant having appeared, judgments of condemnation were entered and the products were ordered destroyed.

741. Misbranding of Optic Drop. U. S. v. 20 Bottles of Optic Drop. Default decree of condemnation and destruction. (F. D. C. No. 3828. Sample No. 6978–E.)

The labeling of this product bore false and misleading representations regarding its efficacy in the conditions indicated below. The volume of the carton was more than 5 times the volume of the bottle and certain mandatory labeling requirements of the law were not complied with.

On February 19, 1941, the United States attorney for the District of New Mexico filed a libel against 20 bottles of Optic Drop at Albuquerque, N. Mex., alleging that the article had been shipped in interstate commerce on or about October 4, 1940, by the Romero Drug Co. from El Paso, Tex.; and charging that it was misbranded.

Analysis showed that the article consisted essentially of a water solution of zinc sulfate, chlorobutanol, a berberine salt, boric acid, and/or a borate.

It was alleged to be misbranded: (1) In that the statement "For irritated Eyes" and the Spanish translation of the same statement "Para Ojos irritados," appearing in the labeling, were false and misleading, since it was not an adequate or appropriate treatment for all irritations of the eyes. (2) In that the following statements (in Spanish) in the labeling were false and misleading, since it would not fulfill the promise of benefit stated and implied thereby: (Translation from Spanish) "It is well known that the eyes are constantly exposed to the bright and burning light of the sun, the electric lamp and reflections of the earth; nor do they fail to collect sand, dust and other small particles which imperceptibly float through the air and which greatly affect the vision, causing a certain sensation of itching and even reddening of the eyes. This occurs chiefly in those who work in shops, trains, factories or any other places of movement and commotion. Now then, in order to constantly protect the sight at such times, one should always have on hand a bottle of Gota Optica, an admirable, scientifically prepared lotion for the eyes which not only soothes, refreshes and cleanses the eyes and eyelids but alleviates the irritation, removing the foreign substances which may have lodged in them. This is why the Gota Optica has been and is now highly recommended by all the most celebrated opticians." (3) In that the label failed to bear the common or usual name of each active ingredient, since of the ingredients only chlorobutanol was mentioned on the label and carton; (4) In that the carton failed to bear a declaration of the quantity of contents of the package. (5) In that its container was so made, formed, and filled as to be misleading.

On April 1, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

742. Misbranding of Utona. U. S. v. 102 Packages of Utona. Default decree of condemnation and destruction. (F. D. C. No. 7006. Sample No. 23117–E.)

On March 11, 1942, the United States attorney for the Northern District of California filed a libel against 102 packages of Utona at San Francisco, Calif., alleging that the article had been shipped in interstate commerce on or about October 18 and December 2, 1941, and January 12, 1942, by the National Utona Co. from Detroit, Mich., and charging that it was misbranded.

Analysis showed that the article consisted essentially of extract of a saponin-bearing plant such as yucca, preserved with salicylic acid and sodium benzoate, colored with caramel and flavored.

The article was alleged to be misbranded in that the statements in the labeling which represented and suggested that it was efficacious as a relief for high blood pressure and would control the pressure and relieve the distressing symptoms; would lower high blood pressure of patients, even those of advanced years, that it would render the body less toxic (poisoned); would bring about marked improvement in older patients through less frequent demands to rise at night to urinate; that it would impart a profound sense of well-being; that it would usually bring about improvement in symptoms such as pain in the back, neck, dizziness, headache, pins and needles sensation; would be efficacious to make one sleep better and feel better and would bring about a better relationship between the systolic and diastolic pressure and that results obtained from its use were such as to warrant clinical study of its effectiveness in the control of hypertension, arteriosclerosis, stroke and kindred conditions, were false and misleading since it would not be efficacious for the purposes so represented and suggested.

On May 19, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

743. Misbranding of Via-Min. U. S. v. 465 Packages of Via-Min. Default decree of condemnation and destruction. (F. D. C. No. 7094. Sample Nos. 90166–E, 90167–E.)

On March 26, 1942, the United States attorney for the District of Massachusetts filed a libel against 465 packages of Via-Min at Boston, Mass., alleging that the article had been shipped in interstate commerce on or about March 7 and 10, 1942, by the Universal Products Co. from Cleveland, Ohio; and charging that it was misbranded.

Analysis of a sample showed that the article contained approximately 2,200 grains per gallon of total solids, i. e., ferric sulfate (not over 1,196 grains), aluminum sulfate (not less than 500 grains), calcium sulfate (16 grains), magnesium sulfate (53 grains), and sodium phosphate (51 grains). The specific gravity varied between 1.018 and 1.027 at 25° C.

The article was alleged to be misbranded: (1) In that the following statements on the label, "Ingredients: Grains per gallon. Specific Gravity 1.049; Ferric Sulphate 1752; Aluminum Sulphate 29; Calcium Sulphate 79; Magnesium Sulphate 409 Sodium Phosphate 70 * * * Total Solids 4,413," were false and misleading since it did not have the total solids or specific gravity stated, and the statements of the amounts of said minerals in grains per gallon were incorrect. (2) In that the statement on the label "used on minor Sores and Cuts," and certain statements contained in an accompanying circular, were false and misleading since they represented and suggested that it would be efficacious in the treatment of minor sores and cuts and in the mitigation, treatment, or prevention of acidosis, acne, eczema, muddy skin, anemia, malnutrition, underweight, arthritis, rheumatism, gout, asthma, auto-intoxication, biliousness, high blood pressure, boils, Bright's disease, bronchitis, colds, sinus trouble, catarrh, constipation, diabetes, falling eyesight, cataract, falling hair, thin hard brittle fingernails, gall-bladder disorders, gallstones, jaundice, goiter, hardening of the arteries, hay fever, stiffness of the joints, leucorrhea, low vitality, lack of endurance, lack of pep, nervousness, sciatic rheumatism, neuralgia, neuritis, nerve exhaustion, obesity, enlarged prostate gland, poor circulation, sexual indifference, tooth decay and spongy gums, gums that bleed easily, tuberculosis of the lungs, and undernourishment of children; that it would build and maintain the bones, teeth, and tendons, counteract acidity, heal wounds, and aid vitality and endurance; that it would be efficacious in the mitigation, treatment, or prevention of tuberculosis, rickets, pyorrhea, heart disease, painful menstruation, anemia, asthma, circulatory diseases, female disorders, and indigestion; that it would build and nourish the brain, nerves, and bones, and would aid in strengthening the mental power; that it would counteract acidosis, purify the blood by eliminating carbon dioxide, and would dissolve hard deposits in the joints; that it would purify the system, aid in keeping the hair, skin, and sex organs in a healthy condition, and intensify the emotions; that it would be efficacious as a nerve sedative; that it would vitalize the lungs and neutralize acid waste materials, and would supply energy and vitality; and that it would be efficacious in producing glossy hair, hard

teeth, keen hearing, sparkling eyes, and would aid greatly in recovery from disease or injury; whereas it would not be efficacious for such purposes.

On May 25, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

744. Misbranding of mercurochrome. U. S. v. 10 Gross Bottles of 2% Solution of Mercurochrome. Default decree of condemnation. Product ordered distributed to charitable institutions. (F. D. C. No. 6731. Sample No. 84851–E.)

This product was short of the declared volume.

On or about January 19, 1942, the United States attorney for the District of Connecticut filed a libel against 10 gross bottles of 2% solution of mercurochrome at New Haven, Conn., alleging that the article had been shipped in interstate commerce on or about December 9, 1941, by Certified Pharmacal Co., Inc., from New York, N. Y.; and charging that it was misbranded in that the statement "Contents 9 cc." was false and misleading as applied to an article in bottles containing less than 9 cc. The article was labeled in part: "2% Solution Mercurochrome * * * Contents 9 cc. * * * Distributed by United First Aid Co., New York, N. Y."

On May 25, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered distributed to charitable institutions.

VETERINARY REMEDIES

745. Misbranding of Lapp's Poultry Blocketts. U. S. v. 10 Cases of Lapp's Poultry Blocketts. Default decree of condemnation and destruction. (F. D. C. No. 6987. Sample No. 68914–E.)

On March 9, 1942, the United States attorney for the District of Kansas filed a libel against 10 cases, each containing 12 cartons, of Lapp's Poultry Blocketts at Topeka, Kans., alleging that the article had been shipped in interstate commerce on or about February 1, 1942, by the Lapp Laboratories, Inc., from Nevada, Iowa; and charging that it was misbranded.

Analysis showed that the article consisted of a mixture of tobacco stems, molasses residue, sodium bicarbonate, and siliceous material.

The article was alleged to be misbranded in that the statements in the labeling which represented and suggested that it was of value in improving production, quality of eggs, and fertility of poultry; was of value in the prevention of intestinal parasites, coccidiosis, simple diarrhea, anemia, and some forms of worms in poultry; and that it was a real poultry regulator, were false and misleading since it would not be of value for such purposes and it was not a poultry regulator.

On April 13, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

746. Misbranding of Wilcoxson's Perfection Liniment. U. S. v. 25 Pint Bottles of Wilcoxson's Perfection Liniment. Default decree of condemnation and destruction. (F. D. C. No. 6993. Sample No. 80373–E.)

On March 10, 1942, the United States attorney for the Eastern District of Kentucky filed a libel against the above-named product at Lexington, Ky., alleging that it had been shipped in interstate commerce on or about August 14, 1941, by the Wilcoxson Remedy Co. from Tiffin, Ohio; and charging that it was misbranded.

Analysis showed that the article consisted essentially of water, alcohol, oil of turpentine, camphor, potassium iodide, and a trace of organically combined iodine.

The article was alleged to be misbranded in that statements in the labeling which represented and suggested that when used as directed on horses, it was a great remedy for bad legs; would allay all fever; would toughen and harden the leg; would remove soreness from spavins, splints, curbs, ringbones, thoroughpins, and all blemishes; and would be efficacious in the treatment of spavins, splints, thoroughpins, ringbone, and all bone enlargements and would be efficacious for back, shoulder and hip lameness and all rheumatic troubles, were false and misleading since when used as directed on horses, it would not accomplish such results.

It was alleged to be misbranded further in that the label failed to bear an accurate statement of the quantity of contents; and in that it was fabricated from two or more ingredients and the label failed to bear the common or usual name of each active ingredient.

On April 15, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

NONSTERILE SURGICAL DRESSINGS

747. Adulteration and misbranding of absorbent cotton. U. S. v. 96 Packages of Absorbent Cotton. Default decree of condemnation and destruction. (F. D. C. No. 6851. Sample No. 70310–E.)

On February 16, 1942, the United States attorney for the Southern District of Florida filed a libel against 96 packages (varying in size from ½ ounce to 16 ounces in size) of absorbent cotton at Tampa, Fla., alleging that the article had been shipped in interstate commerce within the period from on or about November 18, 1941, to on or about January 6, 1942, by the United Drug Co. from Atlanta, Ga.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia and its quality or purity fell below the standards set forth in that compendium since the pharmacopoeia specifies among other things, that absorbent cotton be sterile; whereas the article was not sterile but was contaminated with viable micro-organisms. It was alleged to be misbranded in that the following statements in the labeling, "Absorbent Cotton U. S. P. Double Sterilized * * * The selected high grade cotton in this package has been double sterilized and when sealed, is ready for immediate first aid use," were false and misleading as applied to an article that was contaminated with viable micro-organisms.

On April 23, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

748. Adulteration and misbranding of absorbent cotton. U. S. v. 33,136 Packages of Absorbent Cotton. Consent decree of condemnation. Product ordered released under bond to be resterilized. (F. D. C. No. 7014. Sample No. 70420–E.)

On March 12, 1942, the United States attorney for the Northern District of Georgia filed a libel against the following quantities of absorbent cotton at Atlanta, Ga.—9,080 ½-ounce packages, 14,576 1-ounce packages, 3,230 2-ounce packages, 4,050 4-ounce packages, 1,580 8-ounce packages, and 620 1-pound packages, alleging that the article had been shipped within the period from on or about November 5, 1941, to on or about February 18, 1942, by Absorbent Cotton Co. of America from Valley Park, Mo.; and charging that it was adulterated and misbranded.

It was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, but its quality or purity fell below the standard set forth in the pharmacopoeia since it was not sterile but was contaminated with viable micro-organisms.

It was alleged to be misbranded in that the following statements on the label were false and misleading as applied to an article contaminated with living micro-organisms: "Absorbent Cotton U. S. P. double sterilized * * * The selected high grade cotton in this package has been double sterilized and when sealed, is ready for immediate first aid use."

On April 23, 1942, the United Drug Co., Boston, Mass., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond conditioned that it be resterilized under the supervision of the Food and Drug Administration.

749. Misbranding of Aids Bandages for Emergency Use. U. S. v. 216 Packages of Bandages (and 2 other seizure actions against bandages). Default decrees of condemnation and destruction. (F. D. C. Nos. 6900, 6950, 6953. Sample Nos. 64683–E, 80108–E, 92008–E.)

On February 20 and 26, 1942, the United States attorneys for the Northern District of Ohio, the Western District of Pennsylvania, and the Southern District of California filed libels against 216 packages of bandages at Cleveland, Ohio, 34 dozen packages at Pittsburgh, Pa., and 22 dozen packages at Los Angeles, Calif., alleging that the article had been shipped in interstate commerce on or about November 5 and December 6, 1941, and January 31, 1942, by the Sealtex Co. from Chicago, Ill.; and charging that it was misbranded.

The article was alleged to be misbranded in that the statements "Aids Bandages For Emergency Use * * * Place medicated pad over injury Press edges together Wrap around finger," and the design showing application of the bandage to the finger, appearing in the labeling, were misleading as applied to an article that was not sterile but was contaminated with living micro-organisms.

On March 19 and 21 and April 17, 1942, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

PROPHYLACTICS

750. Misbranding of prophylactics. U. S. v. Penn-Jersey Drug Co., Inc., and Samuel Kohn. Pleas of guilty. Corporation fined $100; Samuel Kohn fined $400. (F. D. C. No. 4112. Sample No. 46322–E.)

On September 18, 1941, the United States attorney for the District of New Jersey filed an information against Penn-Jersey Drug Co., Inc., Newark, N. J., and Samuel Kohn, alleging shipment on or about October 10, 1940, from the State of New Jersey into the State of Pennsylvania of a quantity of prophylactics which were misbranded. The article was labeled in part: "Saf-T-Skin Liquid Latex * * * Gotham-Rubber Co. Chicago New York."

It was alleged to be misbranded in that the statements (cartons and enclosed folders) "The Dependable Prophylactic Saf-T-Skin * * * To Prevent Disease Guaranteed Five Years," were false and misleading since they represented and suggested that it was a safe and dependable prophylactic, would be efficacious in preventing disease, and would be free from defects for a period of 5 years; whereas it was not a safe and dependable prophylactic, it would not be efficacious for preventing disease, and it would not be free from defects for a period of 5 years but was defective because of the presence of perforations or holes.

They were alleged to be misbranded further in that they were in package form and did not contain an accurate statement of the quantity of the contents in terms of numerical count.

On February 27, 1942, pleas of guilty having been entered on behalf of the defendants, the court imposed a fine of $100 against the corporation and $400 against the individual, Samuel Kohn.

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[1] Permanent injunction issued.

[2] Permanent injunction issued; contains findings of fact and conclusions of law.

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FOOD AND DRUG ADMINISTRATION

FEDERAL FOOD, DRUG, AND COSMETIC ACT

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DRUGS FOR HUMAN USE—Continued

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SHIPPERS AND MANUFACTURERS—Continued

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SHIPPERS AND MANUFACTURERS—Continued

[1] Contains instructions to the jury.

SHIPPERS AND MANUFACTURERS—Continued

[1] Permanent injunction issued.

[5] Contains instructions to the jury.

SHIPPERS AND MANUFACTURERS—Continued

SHIPPERS AND MANUFACTURERS—Continued

* Contains instructions to the jury.

SHIPPERS AND MANUFACTURERS—Continued

[1] Permanent injunction issued.

[4] Permanent injunction issued; contains findings of fact and conclusions of law.

SHIPPERS AND MANUFACTURERS—Continued

SHIPPERS AND MANUFACTURERS—Continued

SHIPPERS AND MANUFACTURERS—Continued

[1] Permanent injunction issued.

[2] Contains an opinion of the court.

U. S. GOVERNMENT PRINTING OFFICE: 1949

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

751–800

DRUGS AND DEVICES

The cases reported herewith, commenced prior to June 30, 1940, were instituted in the United States District Courts by the United States attorneys acting upon reports submitted by direction of the Secretary of Agriculture; and those commenced on and after that date were similarly instituted upon reports submitted by direction of the Federal Security Administrator.

PAUL V. MCNUTT, *Administrator, Federal Security Agency.*

WASHINGTON, D. C., *July 19, 1943.*

CONTENTS [1]

DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

751. Action to enjoin and restrain interstate shipments of a drug designated as Dependon Products Intrauterine Paste and the same drug designated as Dependon Products Paste. U. S. v. Anne M. Jenks doing business as Dependon Products and Jenks Physicians' Supplies. Permanent injunction granted. (Inj. No. 35.)

On October 16, 1942, the United States attorney for the District of Minnesota filed a complaint against Anne M. Jenks, doing business as Dependon Products and Jenks Physicians' Supplies at White Bear Lake, Minn., alleging that since 1930 the defendant had been the sole owner and operator of said business and had been engaged in the sale and distribution of gynecological specialties; that about the latter part of 1938 the defendant had become engaged in the sale and distribution in interstate commerce of an article labeled in part, "Dependon Products Intrauterine Paste"; that the article was offered for sale for injection into the pregnant uterus and as an effective medicament for the treatment of abnormal conditions which prevail in a nonpregnant uterus; that it was a viscous yellowish liquid consisting of a water solution of potassium soap, alcohol, glycerin, and iodine compounds and was a drug within the meaning of the law; that accompanying said drug in interstate commerce so as to consti-

[1] For reduction of quality because of extraneous material, see No. 756 (triple-distilled water); omission of, or unsatisfactory, active ingredients statements, Nos. 754, 756–758, 761, 764, 775, 782, 790, 791, 793; inconspicuousness of warning statement, No. 754; omission of name and place of business of manufacturer, packer, or distributor, No. 758; omission of accurate statement of quantity of contents, Nos. 758, 760; deceptive packaging, No. 782, 790, 791.

tute labeling within the meaning of the law was a circular specifying the dosage, frequency, and duration of administration.[2]

The complaint alleged further: I. That the drug was misbranded: (1) In that it was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling for the purposes of terminating pregnancy, for inducing labor, and for removing the retained portions of the products of conception. (2) In that the words "Intrauterine Paste," borne on the label, and statements in an accompanying circular represented and suggested that it was safe and appropriate for introduction into the uterine cavity for the purposes of terminating pregnancy, for inducing labor, and for removing retained portions of the products of conception; whereas it was not safe or appropriate for such purposes but was unsafe and dangerous and was capable of producing serious or even fatal consequences. (3) In that the following statements, "For Dysmenorrhea From 5 to 10 cc's of the Paste applied shortly before the period is considered helpful in some cases. The insertion of the Cannula may be considered to act as a dilatation. For Endometritis Cervical and Uterine Discharges. Application of from 5 to 10 cc's of the paste, as needed, is suggested by many physicians," represented and suggested that it was an effective medicament for the treatment of dysmenorrhea, endometritis, and cervical and uterine discharges; whereas it was not an effective medicament for such purposes.

II. (1) That in or about December 1941, and since that time up to the filing of the complaint, the drug had been subject to numerous libel or seizure actions commenced by the Government in various Federal judicial districts throughout the country for the purpose of condemning the quantities seized as misbranded within the meaning of the law; that in at least five instances decrees in favor of the United States had been entered condemning, forfeiting, and ordering destruction of the seized goods; and that other cases were awaiting trial. [These have since been terminated by the entry of decrees in favor of the Government.] (2)

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[2] The following statements appeared in the circular: "For Physicians Only Nod-Nep-Ed Sterile Intrauterine Paste * * * Non-Toxic * * * Instillation of the Paste may be made by means of a Cannula attached to the tube, or by transferring the Paste to a syringe and then attaching the special syringe type Cannula to the syringe. * * * When using the Paste to terminate a pregnancy, or to induce labor it is usually considered that best results are obtained when the available space in the uterus is filled with the Paste. * * * Dependon Intrauterine Paste should be used only by a Physician, with adequate and continuous supervision of the case. For Therapeutic Termination of Pregnancy * * * Technique of Application of Paste—With self-supporting vaginal speculum in place, *very* slowly pass Cannula thru cervix until the tip has reached the uterine cavity. During this procedure keep expelling small amounts of the Paste. Thus the canal is continually lubricated and readily opened. After Cannula has reached the uterine cavity, even more slowly continue its insertion until a slight back pressure is felt—then slightly withdraw Cannula and turn it to one side (quarter turn)—now instill the desired amount of Paste into the uterus. If the uterus tips forward, the Cannula is turned to point downward. Undue pressure in applying the Paste must be avoided—should tension, pain, bleeding or expulsion of Paste develop, arrest instillation. After Paste instillation keep patient in Trendelenburg's position (hips higher than shoulders) for some moments. Later when Patient is resting she should be advised to place feet higher than her head. Should the cervical canal be enlarged, a small amount of sterile cotton may be placed so as to retain the Paste. The use of a rubber plug for this purpose is not recommended. Treatment during early stages of pregnancy: Dependon Intrauterine Paste may be used in the very early stages. Extreme gentleness and care is advised at this difficult time. It is essential that the Paste be deposited at the vault of the uterus, otherwise some bleeding; but no evacuation may be the result. Depending on the size of the uterus, from 10 to 15 cc's applied after effects of sedatives are noted, is suggested. Treatment during later stages of pregnancy: (after eight weeks)—Best dosage is usually from 7 to 10 cc's per month of pregnancy. Larger dosages (up to capacity of uterus to receive Paste) often produce stronger and quicker action. Maximum dosage, ordinarily should not exceed 30 to 40 cc's. Precautions—Always before using Paste a careful diagnosis should be made. * * * Under some conditions the Paste may not bring on the desired results. * * * It may also be observed that unless the Paste is properly placed and in sufficient amount, no results following its use may be looked for. In cases where the Paste fails to bring the desired results, and there are no contra-indications for its use, it is the usual practice to repeat the treatment after a few days * * * Then pains set in with rhythmic and sustained contractions. * * * In a few cases, spotting may be looked for, following the Paste treatment. This condition may ordinarily be expected to shortly correct itself. However, if spotting continues over a period of weeks, the possibility of only partial expulsion should be considered and proper therapy instituted. Generally massage of the uterus is sufficient. * * * Comments of Physicians indicate that *practically every case is uneventful,* and that in the very rare event that the Paste fails to bring the desired results no harm develops from the trial of the Paste treatment. We believe this is due to the fact that Dependon Intrauterine Paste is nontoxic and sterile. For Induction of Labor. Dosage is usually from 30 to 40 cc's, accompanied by quinine or other indicated therapy. For Incomplete Miscarriage. Usually from 10 to 15 cc's of the Paste is sufficient. Proper therapy should accompany use of Paste. * * * When using Dependon Intrauterine Paste it is suggested that a syringe be employed in some cases. * * * pressure can be accurately controlled. * * * In cases where Paste is used for the therapeutic termination of pregnancy * * * as the ability to conceive seems to be greatly enhanced following use of Dependon Intrauterine Paste."

That notwithstanding the fact that the Federal Security Agency had informed the defendant the drug was dangerous to health and misbranded in violation of the law, she in complete disregard of the decrees which had been entered condemning the drug had continued to introduce or deliver it for introduction into interstate commerce. (3) That in or about April 1942, the defendant relabeled her product under the name of "Dependon Products Paste," but that it was in fact the same drug as that formerly known as Dependon Products Intrauterine Paste; and that although she was not shipping it under the former designation, she was continuing to ship the same product under the latter designation to and through States other than Minnesota.

III. That the drug labeled "Dependon Products Paste" was misbranded: (1) In that it was dangerous to health when used in the dosage prescribed, recommended, and suggested in the labeling, namely, "The use of this product in uterine therapy (which is still medically controversial) should be by physicians only * * * maximum dosage * * * in pregnant uterus 30 C. C. actual dosage to be determined by the physician for the individual patient." (2) In that the statements, "Dependon Products Paste * * * The use of this product in uterine therapy (which is still medically controversial) should be by Physicians only. * * * Maximum dosage to be determined by the Physician for the individual patient. Undue pressure in applying paste must be avoided," represented and suggested that it was safe and appropriate for introduction into the pregnant uterus; whereas it was not safe and appropriate for such purpose but was unsafe and dangerous and capable of producing serious injury or even fatal consequences. (3) In that the said statements represented and suggested that it was an effective medicament for the treatment of abnormal conditions in a nonpregnant uterus; whereas it was not an effective medicament for such purposes.

IV. That the shipments subsequent to 1938 of Dependon Products Intrauterine Paste and subsequent to April 1942 of Dependon Products Paste were in violation of section 301 of the act which makes it a criminal offense to cause the introduction or delivery for introduction into interstate commerce of an adulterated or misbranded drug; and that in order to protect the public of the United States from dangers inherent in the use of the article it was necessary that an injunction issue; and praying that after proper notice and hearing a preliminary injunction issue restraining such unlawful acts by the defendant, and that after due proceedings the preliminary injunction be made permanent.

On October 29, 1942, the defendant having filed an answer denying the material allegations of the complaint and having appeared by counsel, the case came on for hearing to show cause why a temporary injunction should not issue. As a result of the hearing, the court found in substance that the defendant was engaged in the distribution in interstate commerce of the drug product alleged in the complaint, that it was offered for the purposes therein alleged, that the court had jurisdiction to restrain violations of section 301 of the act "for cause shown," and that irreparable injury need not be established as a prerequisite to the issuance of such preliminary injunction. The court stated further that the position taken by the Government was supported by the sworn statement of three leading doctors and that sufficient cause for the issuance of a temporary injunction had been shown; and on October 31, 1942, a temporary injunction against the defendant was entered.

On January 5, 1943, the case came on for trial on the merits as to why a permanent injunction should not issue, the trial continuing until and through January 18, 1943. During the trial no evidence was introduced on behalf of the defendant in opposition to the contentions of the Government; and on January 19, 1943, the court after consideration of the evidence submitted by the Government in the form of files, records, and exhibits, of the testimony of witnesses, and of arguments of counsel, made the following Findings of Fact, Conclusions of Law, and Order for Judgment (BELL, *District Judge*):

FINDINGS OF FACT

I

"Defendant, Anne M. Jenks, resides in the City of White Bear Lake, Ramsey County, State of Minnesota, and within the jurisdiction of this court, where for a number of years she has been engaged under the name and style of Dependon Products and Jenks Physicians' Supplies in the sale and distribution in interstate commerce of gynecological specialties.

II

"Since about 1933 defendant has manufactured, sold, and distributed in interstate commerce an article which has been labeled in part as 'Intrauterine Paste Gynecological Soap' and 'Dependon Products Paste'; said article has been composed mainly of potassium soap or other soft soap base, with small quantities of alcohol, iodine, and distilled water added, although its formula and composition has not been entirely consistent; said article is offered for sale and intended for use by licensed physicians in the performance of therapeutic abortions, in the treatment of incomplete abortions and miscarriages, for the induction of labor and as a medicament for the treatment of endometritis, cervicitis, dysmenorrhea, and cervical and uterine discharges.

III

"In connection with the interstate distribution of the said article, defendant has distributed written, printed, and graphic matter in the form of circulars containing suggestions and recommendations as to usage, technique of use, dosage, frequency, and duration of administration—at times, by enclosing the same in the retail cartons containing said article, and at times by enclosing the same in the shipping carton in which several of said retail cartons have been shipped in interstate commerce, and at other times by sending such matter by separate mail at or about the same time the article itself was shipped: that where the latter practice has been followed, the article and such matter, although separately shipped, arrived at destination at or about the same time.

IV

"Such written, printed, and graphic matter as well as the various labels which have been affixed to said article, represent and suggest that said article is safe and appropriate for introduction into the pregnant uterus, for the purpose of inducing labor, terminating pregnancy, and removing the retained portions of the products of conception.

V

"Such written, printed, and graphic matter as well as the various labels which have been affixed to said article, represent and suggest that said article is an effective medicament for the treatment of cervicitis, endometritis, dysmenorrhea and cervical and uterine discharges.

VI

"Said article when used for the purposes of the induction of labor, termination of pregnancy, and the removal of the retained portions of the products of conception, is unsafe and dangerous to health and has caused fatalities and serious injury. Among the specific dangers which are involved in and have resulted from its use are the extensive destruction of tissue, hemolysis or the destruction of the cellular portions of the blood, systemic potassium poisoning, extensive hemorrhage and prolonged bleeding, sterility, peritonitis, pulmonary embolism, damage to kidneys, liver and other internal organs, and increased susceptibility to infection.

VII

"The dangers to health hereinbefore enumerated in Paragraph VI for the most part are the result of the physiological action of the soap ingredient present in said article or any article of drug having soap as a base.

VIII

"The dangers to health hereinbefore enumerated in Paragraph VI are present when said article is used by licensed physicians or anyone, in any quantity, or for any duration, or with any frequency of usage, for the treatment of any conditions which prevail in the pregnant uterus.

IX

"Said article is ineffective for the treatment of cervicitis, endometritis, dysmenorrhea, and cervical and uterine discharges, or the treatment of any other condition prevailing in a non-pregnant uterus.

X

"Heretofore on October 31, 1942, this court made its order that a temporary injunction should issue restraining defendant and any of her agents or associates from introducing or delivering for introduction into interstate commerce, and from causing the introduction or delivery for introduction into interstate commerce of said article or an article of substantially similar composition.

XI

"The dangers inherent in the use of said article, or any other article having a soap for its base, with or without small quantities of iodine, alcohol, and distilled water added, when used for introduction into a pregnant uterus, and its ineffectiveness when used for the conditions suggested in a non-pregnant uterus, make essential the issuance of a permanent injunction restraining henceforth the interstate distribution of said article for introduction into a pregnant or non-pregnant uterus, or for any other purpose unless application therefor is made to the court."

CONCLUSIONS OF LAW

I

"The court is specifically authorized by section 302 (a) of the Federal Food, Drug, and Cosmetic Act to restrain the introduction or delivery for introduction or the causing of the introduction or delivery for introduction into interstate commerce of a drug which is misbranded.

II

"Cause has been shown justifying the issuance of a permanent injunction.

III

"Said article, whether labeled in part 'Intrauterine Paste Gynecological Soap' or 'Dependon Products Paste' is a drug within the meaning of section 201 (g) (2) and (3) of said act.

IV

"The written, printed, or graphic matter distributed by defendant enclosed either in retail cartons containing said drug or within shipping packages containing said retail cartons, or shipped separately from said drug accompanies said drug within the meaning of section 201 (m) of the act and hence constitutes 'labeling.' The labels which have been affixed by defendant to said drug also constitute 'labeling' within the meaning of section 201 (m).

V

"Said drug is misbranded within the meaning of section 502 (a) of said act in that its labeling is false and misleading, for the reason that it represents and suggests that said drug when used for induction of labor, termination of pregnancy, or the removal of the retained portions of the products of conception, is safe and appropriate; whereas in truth and in fact it is unsafe and dangerous and has caused serious and fatal consequences.

VI

Said drug is misbranded within the meaning of section 502 (a) of said act in that its labeling is false and misleading for the reason that it represents and suggests that said drug is an effective medicament for the treatment of cervicitis. endometritis, dysmenorrhea, and uterine and cervical discharges; whereas in truth and in fact it is ineffective for such purposes.

VII

"Said drug is misbranded within the meaning of section 502 (j) in that it is dangerous to health when used in any dosage or with any frequency or with any duration of administration prescribed, recommended, or suggested in its labeling, for the purposes of induction of labor, termination of pregnancy, and removal of the retained portions of the products of conception.

ORDER FOR JUDGMENT

"Upon the basis of the foregoing Findings of Fact and Conclusions of Law,
"It is hereby *Ordered*, That a Permanent Injunction be entered accordingly, without costs to either party."

PERMANENT INJUNCTION

"It is hereby *Ordered and Decreed*, That defendant, her employees, servants, agents, distributors, assigns, and any and all persons in active concert or participation with them be, and they are, hereby permanently enjoined from introducing or delivering for introduction into interstate commerce and from causing the introduction or delivery for introduction into interstate commerce of the article of drug, labeled in part, 'Intrauterine Paste' or 'Dependon Products Paste,' or under any other name, containing soft soap or other soap base with or without distilled water, iodine, and alcohol or other ingredients added, under labeling recommending or suggesting its use for introduction into the uterus for the purpose of terminating pregnancy, treating incomplete abortions or miscarriages, for inducing labor, or as a medicament for the treatment of dysmenorrhea, endometritis, cervicitis, cervical or uterine discharges, or for any intrauterine or cervical therapy whatever.
"In order to effectuate the purposes of the act and to prevent the article of drug from being used in uterine and cervical therapy, defendant, her employees, servants, agents, distributors, assigns, and any and all persons in active concert or participation with them, are specifically enjoined from introducing or delivering for introduction or causing the introduction or delivery for introduction into interstate commerce of said article of drug or any similar article of drug for any purpose whatsoever in violation of the Federal Food, Drug, and Cosmetic Act, and amendments thereto."

752. Introduction and delivery for introduction in interstate commerce of quantities of Dependon Products Paste in violation of preliminary injunction. U. S. v. Anne M. Jenks, W. S. Jenks, and C. H. Jenks. Plea of guilty by W. S. Jenks; fine $500. Plea of not guilty by Anne M. Jenks. Tried to the court. Judgment of guilty; fine $250. Action against C. H. Jenks dismissed. (Inj. No. 35.)

On January 19, 1943, the United States attorney for the District of Minnesota filed an information against Anne M. Jenks, W. S. Jenks, and C. H. Jenks, alleging that Anne M. Jenks was trading as the Dependon Products and Jenks Physicians' Supplies at White Bear Lake, Minn., that defendant W. S. Jenks was the husband and that defendant C. H. Jenks was the brother-in-law of the said Anne M. Jenks, and that the two defendants last named were at that time actively associated with her in the business and on the dates hereinafter mentioned were the agents of and were acting in concert with defendant Anne M. Jenks.
The complaint alleged further that an injunction proceeding was commenced under section 302 of the Federal Food, Drug, and Cosmetic Act by the filing on October 16, 1942, of a complaint and petition for issuance of an order to show cause why a temporary injunction should not issue restraining the defendant Anne M. Jenks, her agents, and all those acting on her behalf from introducing or delivering for introduction into interstate commerce a drug product under the name "Dependon Products Intrauterine Paste" or the same product under the name "Dependon Products Paste," and that on October 29, 1942, a preliminary injunction issued in accordance with the prayer of said complaint; that on or about November 15, 1942, Anne M. Jenks knowingly and willfully, in violation of the preliminary injunction, introduced or delivered for introduction or caused such delivery or introduction into interstate commerce from White Bear Lake, Minn., by making personal delivery of 2 tubes of Dependon Products Paste to a physician at Hannibal, Mo., in contemptuous disregard of the preliminary injunction.
The information alleged further that since January 1, 1943, the three above-named defendants had introduced or delivered for introduction into interstate commerce from White Bear Lake, Minn., (or, had caused such acts) various quantities of the said drug under the designation "Dependon Products Paste" to various physicians in the States of Missouri, Iowa, Oklahoma, Wisconsin, Pennsylvania, and Massachusetts, in contempt of the preliminary injunction and that such acts were willfully and knowingly made in violation of the said injunction.
On January 19, 1943, the defendants were arraigned and W. S. Jenks entered a plea of nolo contendere, which plea was rejected by the court, whereupon he

entered a plea of guilty. The defendant Anne M. Jenks, having entered a plea of not guilty, the charges against her were tried to the court. The Government produced no witnesses but evidence was introduced by and on behalf of the defendants. Judgment was entered by the court finding Anne M. Jenks guilty. The court thereupon imposed a fine of $500 against W. S. Jenks and a fine of $250 against Anne M. Jenks. No evidence of any violation of the law by the defendant C. H. Jenks having been introduced, the action against him was dismissed.

753. Misbranding of intrauterine paste. U. S. v. 22 Tubes of Intrauterine Paste (and 9 other seizure actions against intrauterine paste). Default decrees of condemnation and destruction. (F. D. C. Nos. 6564, 6567, 6571, 6574, 6579, 6580, 6590, 6613, 6690, 6745. Sample Nos. 16897–E, 16898–E, 22398–E, 23114–E, 48990–E, 48991–E, 71514–E, 84674–E, 90131–E.)

Between December 26, 1941, and January 22, 1942, the United States attorneys for the Southern District of New York, Western District of Missouri, District of Massachusetts, Northern District of Georgia, and the Northern District of California filed libels against 22 tubes of intrauterine paste at New York, N. Y.; 49 cartons, each containing 1 tube of intrauterine paste at Kansas City, Mo.; 13 tubes at Chillicothe, Mo.; 33 tubes at Medford, Mass.; 27 tubes at Atlanta, Ga.; and 36 tubes at San Francisco, Calif., alleging that the article had been shipped in interstate commerce within the period from on or about September 28, 1941, to on or about January 2, 1942, in part under the name Dependon Products from St. Paul, Minn., and in part under the name Jenks Physicians' Supplies from White Bear Lake, Minn.; and charging that it was misbranded.

The article was alleged to be misbranded in that it would be dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, or suggested in the labeling. It was alleged to be misbranded further in that the statement "Intrauterine Paste," borne on the labels, represented and suggested that it would be safe and appropriate for introduction into the uterine cavity; whereas it was not safe or appropriate for introduction into the uterine cavity, but was unsafe and dangerous and was capable of producing serious and even fatal consequences.

On February 27 and 28 and September 28, 1942, no claimant having appeared for the seizures at New York, Kansas City, and Chillicothe, and one of the seizures (involving 6 tubes) at San Francisco, Calif., judgments of condemnation were entered and the product was ordered destroyed in each instance, with the exception of the lot seized at New York, N. Y., which was ordered delivered to the Food and Drug Administration.

On March 12, 1942, Anne M. Jenks, trading as Dependon Products and Jenks Physicians' Supplies, having entered an appearance in the district court for the District of Massachusetts and stipulations having been entered between the claimant and the United States attorney for consolidation of the cases instituted in the District of Massachusetts, the Northern District of Georgia, and the seizure of 30 tubes of Dependon Paste at San Francisco, Calif., and the removal of the cases to the Western District of Wisconsin, the court ordered the consolidation and transfer of said cases as stipulated.

On April 1, 1943, no claim or answer having been filed and the intervener having stipulated that the appearance of counsel be withdrawn and that further proceedings should be had as upon default, judgments of condemnation were entered and the product was ordered delivered to the Food and Drug Administration.

754. Misbranding of Luebert's preparations. U. S. v. 4¾ Dozen Boxes of Luebert's (Nox'em Brand) Iron Tonic Compound Tablets, 2¾ Dozen Boxes of Luebert's Ka-No-Mor Capsules, and 2⅔ Dozen Boxes of Luebert's Noxem Brand Tablets and Capsules (Combined). Default decree of condemnation and destruction. (F. D. C. No. 6837. Sample Nos. 54634–E to 54636–E, incl.)

This case was based upon the following violations: Drugs containing acetanilid and dangerous to health when used with the frequency and duration recommended in the labeling—Ka-No-Mor Capsules and Noxem Brand Tablets and Capsules (Combined); labeling failing to bear adequate warning statements and containing false and misleading therapeutic claims—all three products; failure to bear adequate directions for use—Ka-No-Mor Capsules; failure to bear satisfactory active ingredient statements—Iron Tonic Compound Tablets and Noxem Brand Tablets and Capsules (Combined); and inconspicuousness of warning statement—Ka-No-Mor Capsules.

On or about February 14, 1942, the United States attorney for the District of Delaware filed a libel against the above-named drug preparations at Wilmington, Del., alleging that they had been shipped in interstate commerce on or about May 17 and June 27, 1941, by A. G. Luebert, P. D.; and charging that they were misbranded.

Analysis of Luebert's Iron Tonic Compound Tablets showed that they consisted essentially of salts of iron and manganese, strychnine sulfate, arsenic trioxide, a phosphide, and fish oil. They were alleged to be misbranded: (1) In that the labeling failed to warn against their use by children and by elderly persons because of their strychnine content, and it also failed to warn against taking more than the recommended dose and against frequent or continued use because of their strychnine and arsenic content. (2) In that the statements in the labeling which represented and suggested that they would produce rich blood, good health, strong nerves, and astounding vitality; would give strength and vigor to the entire system; would cleanse the blood after the accumulations of the winter months; would benefit those who are weak, run-down, or depressed; would insure a vigorous condition of the nervous system; would produce proper activity of all the organs and functions of the body; would stimulate the nutritive functions; would act as a general tonic to the digestive tract; would be efficacious for those conditions which call for an effective tonic, such as loss of appetite and a tired run-down feeling; and that they were solely an iron tonic, were false and misleading since they would not produce such effects, and they contained physiologically active drugs in addition to an iron compound. (3) In that they were fabricated from two or more ingredients and their label failed to bear a statement of the quantity or proportion of strychnine sulfate and arsenic trioxide that they contained.

Analysis of the Ka-No-Mor Capsules showed that they contained acetanilid (3 grains per capsule), caffeine, and aspirin. They were alleged to be misbranded: (1) In that they would be dangerous to health when used with the frequency or duration recommended in the labeling. (2) In that the labeling failed to warn against their use by children; and against unsafe dosage or duration of administration since the box labels failed to restrict the number of doses, and although the circular restricted their use to five capsules a day, such use constituted an excessive dosage of acetanilid. (3) In that the directions for use provided for administration of an excessive amount of acetanilid. (4) In that the warning against use in those pathological conditions where their use might be dangerous to health did not appear in the labeling with such conspicuousness as to render it likely to be read by the ordinary individual under customary conditions of purchase and use. (5) In that certain statements in the labeling which represented and suggested that when used as directed the capsules constituted a safe and appropriate treatment for the relief of pain and discomfort of simple headache, neuralgias, and muscular aches and pains, for pain following tooth extraction, for helping to allay functional menstrual pains, for common colds, for helping to allay feverish conditions in colds, and for rheumatic pains, were false and misleading since they did not constitute a safe and appropriate treatment for such conditions but were a dangerous drug; and the label failed to reveal the material fact that their use in accordance with the directions might cause serious blood disturbances, anemia, collapse, or a dependence on the drug.

Analysis of Luebert's Noxem Brand Tablets and Capsules (Combined) showed that the tablets consisted essentially of sodium salicylate, caffeine, strychnine sulfate, and a laxative plant drug; and that the capsules consisted essentially of acetanilid (3 grains per capsule), aspirin, and caffeine. They were alleged to be misbranded: (1) In that they would be dangerous to health when used with the frequency or duration recommended in the labeling. (2) In that the labeling failed to warn (a) that they should not be given to children because of their acetanilid and strychnine content; (b) that they should not be used by elderly persons because of their strychnine content; (c) that they could not be safely administered over a long period of time because they contained strychnine; (d) that because of their acetanilid content frequent or continued use might result in serious blood disturbances, anemia, collapse, or dependence upon the drug; and (e) against unsafe dosage of an article containing acetanilid and strychnine. (3) In that representations in the labeling that they were an adequate treatment for rheumatic fever and were an appropriate treatment for aches and pains of neuralgia, gout, and muscles, were false and misleading since they would not be efficacious for such purposes. (4) In that the label failed to declare one of the active ingredients under its common or usual name, i. e., aspirin; and to bear a statement of the quantity or proportion of strychnine sulfate that was present.

On April 20, 1942, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

755. Adulteration and misbranding of Gilmore's Headache Powders. U. S. v. 45 Packages of Gilmore's Headache Powders. Default decree of condemnation and destruction. (F. D. C. No. 7354. Sample No. 86370–E.)

This product, in addition to being dangerous to health when used according to directions, failed to bear adequate directions for use and warning statements in the labeling, and contained acetanilid, caffeine citrate, and sodium bicarbonate greatly in excess of the amounts declared on the label.

On April 16, 1942, the United States attorney for the Northern District of Indiana filed a libel against 45 packages of the above-named article at Fort Wayne, Ind., alleging that it had been shipped in interstate commerce on or about November 11 and December 9, 1941, by the Don Gilmore Laboratories, Inc., from Cleveland, Ohio; and charging that it was adulterated and misbranded. The article was labeled in part: "Each Powder contains 2½ grains Acetanilid * * * ¾ grain Caffeine Citrate, ¾ grain Sodium Bicarbonate."

Analysis of a sample of the article showed that each powder contained 6.93 grains of acetanilid, 2.61 grains of caffeine citrate, and 2.50 grains of sodium bicarbonate.

It was alleged to be adulterated in that its strength differed from that which it purported or was represented to possess.

It was alleged to be misbranded: (1) In that it would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling, namely, "Directions: Place a powder on the tongue and swallow with water. Repeat in twenty minutes if necessary," since when taken in accordance with these directions the powders would provide for the administration of slightly less than 14 grains of acetanilid in 20 minutes. (2) In that the labeling failed to bear adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health, or against unsafe dosage or methods or duration of administration, in such manner and form as are necessary for the protection of users, since the powders contained acetanilid and the labeling contained no warning that frequent or continued use might be dangerous, causing serious blood disturbances, anemia, collapse, or dependence on the drug; and, further, that the powders should not be given to children. (3) In that the label failed to bear adequate directions for use. (4) In that the statement on the label, "Each Powder contains 2½ grains Acetanilid * * * ¾ grain Caffeine Citrate, ¾ grain Sodium Bicarbonate," was false and misleading.

On July 1, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS[3]

756. Adulteration of triple distilled water and sterile solution of epinephrine chloride; misbranding of Suppletive Formula No. 1, Sterile Supportive Formula S. G. M. a., Sterile Solution Formula No. 1, Compressed Tablets No. 358, and Compressed Tablets Thyroid; adulteration and misbranding of Neohormestrin, solution of quinine and urea hydrochloride, quinine sulfate tablets, and sterile solution of ovarian extract. U. S. v. E. S. Miller Laboratories, Inc. Plea of nolo contendere. Fine, $75 on each of 4 counts. Imposition of sentence suspended on remaining counts and defendant placed on probation for 1 year. (F. D. C. No. 4132. Sample Nos. 7368–E, 7397–E, 7655–E, 7939–E, 30843–E, 31909–E, 31912–E, 32631–E, 53828–E to 53831–E, incl., 53833–E, 55734–E.)

This case involved the following violations and products: Failure to bear adequate directions, adequate warning statements, and satisfactory ingredient statements, Suppletive Formula No. 1 and Sterile Solution No. 1; failure to bear adequate directions and warnings, Compressed Tablets No. 358 and Compressed Tablets Thyroid; failure to bear adequate directions and ingredient statements, Sterile Supportive Formula S. G. M. a.; failure to comply with own standard of strength and quality and to bear satisfactory ingredient statement, Neohormestrin; failure to comply with official standard and reduction of quality because of the presence of minute particles of rubber, triple distilled water; failure to comply with official standards of strength and quality, quinine and urea hydrochloride, quinine sulfate, and epinephrine chloride.

[3] See also Nos. 754, 755.

On February 16, 1942, the United States attorney for the Southern District of California filed an information against E. S. Miller Laboratories, Inc., Los Angeles, Calif., alleging shipment within the period from on or about April 30, 1940, to on or about March 28, 1941, from the State of California into the States of Arizona, Illinois, and Oregon of quantities of the above-named drugs which were adulterated and/or misbranded.

The Suppletive Formula No. 1 was alleged to be misbranded in that its labeling failed to bear (1) adequate directions for use; and (2) adequate warnings against use in those pathological conditions where its use might be dangerous to health or against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users since it contained emetine hydrochloride, and warnings that its use might cause vomiting, nausea, heart, kidney, stomach, or intestinal injury or disease unless administered in restricted dosage by a physician; and that it should not be administered over a continued period of time because of its cumulative toxic effects. It was alleged to be misbranded further in that its label did not bear the common or usual name of the drug contained therein, i. e., emetine hydrochloride.

The Sterile Solution Formula No. 1 was alleged to be misbranded in that its label failed to bear adequate directions for use and adequate warnings against use in those pathological conditions where its use might be dangerous to health, or against unsafe dosage or methods or duration of administration since it contained emetine and its labeling failed to bear warnings that its use might cause nausea, vomiting, heart, kidney, stomach, or intestinal diseases, that it should not be used in the presence of such pathological conditions; and that it might be especially dangerous for elderly persons and should not be administered to individuals suffering from high blood pressure, heart disease, diabetes, or thyroid trouble except when administered by a physician. It was alleged to be misbranded further in that it was fabricated from two or more ingredients and its label failed to bear the common or usual name of each active ingredient.

The Compressed Tablets No. 358 were alleged to be misbranded in that the labeling did not bear adequate directions for use since it bore no directions at all; and in that it failed to bear adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health, or against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users since its labeling did not bear warnings that the tablets contained acetanilid frequent or continued use of which might be dangerous, causing serious blood disturbances, anemia, collapse, or dependence on said drug, and that it should not be given to children.

The Compressed Tablets Thyroid Substance were alleged to be misbranded in that the labeling did not bear adequate directions for use since it bore no directions at all; and in that the labeling failed to bear adequate warnings against use in those pathological conditions or by children where such use might be dangerous to health, or against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users, since the article contained thyroid and the labeling failed to bear a warning that it might cause adverse effects on the body metabolism and the cardiovascular and central nervous systems, and that it should not be used by persons afflicted by heart disease or hyperthyroidism.

The Sterile Solution Neohormestrin was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and was represented to possess since the labels of all 3 shipments represented that it possessed in each cubic centimeter a potency equivalent to that possessed by 2,500 International Units of oestrus-producing hormone and the label of one of the shipments represented that each cubic centimeter possessed a potency equivalent to that possessed by 500 Allen-Doisy rat units, namely, 500 rat units of oestrus-producing hormone; whereas it possessed a potency lower than that represented, tests of the three shipments having shown the following results: No. 1 was inert, No. 2 had a potency equivalent to that possessed by not more than 75 International Units of oestrus-producing hormone, and No. 3 had a potency equivalent to that possessed by not more than 55 International Units of oestrus-producing hormone equivalent to not more than 11 Allen-Doisy rat units. It was alleged to be misbranded in that the statements on the label, (2 shipments) "1 c. c. contains 2500 International Units Oestrus Producing Hormone," and (3d shipment) "Neohormestrin Each c. c. contains 2500 International * * * Units. 500 Rat (Allen-Doisey) Units," were false and misleading. One shipment was alleged to be misbranded further in that it was fabricated from two or more ingredients and its label did not bear the common or usual name of the active ingredient, i. e., oestrus-producing hormones.

The triple distilled water was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the National Formulary but its strength differed from and its quality and purity fell below the standard set forth therein since when tested for oxidizable substances in accordance with the method prescribed in the formulary, it required more than 0.1 cc., namely, 1.6 cc. of twentieth-normal potassium permanganate to maintain a pink color; whereas the formulary provides that triple distilled water when tested in accordance with the method prescribed therein, shall require not more than 0.1 cc. of twentieth-normal potassium to maintain a pink color; and its difference in strength, quality, and purity from such standard was not plainly stated on the label. It was alleged to be adulterated further in that minute particles of rubber had been mixed or packed therewith so as to reduce its quality.

The Ampuls of Sterile Solution Quinine and Urea Hydrochloride were alleged to be adulterated in that they purported to be and were represented as a drug the name of which is recognized in the National Formulary, but their strength differed from and their quality fell below the standard set forth therein since each ampul yielded an amount of anhydrous quinine equivalent to less than 54.8 percent, namely, not more than 49.6 percent of the labeled amount of quinine and urea hydrochloride and 2 cc. of the article contained not more than 12.99 grains (0.838 gram) of quinine and urea hydrochloride; whereas the formulary specifies that unless another concentration of the solution is stated on the label, ampuls of quinine and urea hydrochloride shall contain a sterile solution of approximately 50 grams of quinine and urea hydrochloride in a sufficient quantity of ampul water to make 100 cc. (which is equivalent to 15½ grains (1 gram) of quinine and urea hydrochloride per 2 cc. ampul), and shall yield an amount of anhydrous quinine ($C_{20}H_{24}O_2N_2$) corresponding to not less than 54.8 percent of the labeled amount of quinine and urea hydrochloride; and its difference in strength and quality from such standard was not stated on the label. They were alleged to be misbranded in that the statement on the carton and ampul labels, "2 c. c. * * * Quinine and Urea Hydrochloride 15½ Grains (1.0 Gram)," was false and misleading.

The Sterile Supportive Formula S. G. M. a. was alleged to be misbranded (1) in that its label failed to bear adequate directions for use; and (2) in that it was fabricated from two or more ingredients and its label did not bear the common or usual name of each active ingredient.

The quinine sulfate tablets were alleged to be adulterated in that their strength differed from that which they purported and were represented to possess in that they were represented to contain 5 grains of quinine sulfate; whereas each tablet contained not more than 2.09 grains of quinine sulfate. They were alleged to be misbranded in that the statement "Quinine Sulfate 5 Grs." was false and misleading.

One shipment of Solution Epinephrin Chloride was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia but its quality fell below the standard set forth therein since it contained in each 100 cc. of the solution not more than 0.05 gram of epinephrine; whereas the pharmacopoeia specifies that the article (which is recognized therein under the name "solution of epinephrine hydrochloride") shall consist of "a solution of epinephrine in distilled water and hydrochloric acid, containing in each 100 cc. not less than 0.095 Gm. * * * of $C_9H_{13}O_3N$," and its difference in strength and quality from the pharmacopoeial standard was not plainly stated on the label. The other shipment of Solution Epinephrin Chloride was alleged to be adulterated in that it purported to be and was recognized as a drug the name of which is recognized in the National Formulary but its strength differed from and its quality fell below the standard set forth therein since it contained in each cubic centimeter not more than 0.06 gram of epinephrine; whereas the National Formulary specifies that "Unless otherwise stated on the label, Ampuls of Epinephrine Hydrochloride contain measured quantities of sterile Solution of Epinephrine Hydrochloride (see U. S. Pharmacopoeia XI, page 207)," and the said pharmacopoeia specifies that "Solution of epinephrine hydrochloride is a solution of epinephrine in distilled water and hydrochloric acid, containing in each 100 cc., not less than 0.095 Gm. * * * of $C_9H_{13}O_3N$," and its difference in strength and quality from the standard set forth in the formulary was not plainly stated on the label.

The Solution of Ovarian Extract was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and

was represented to possess in that it was represented to contain in each cubic centimeter not less than 50 rat units of ovarian extract; whereas it contained in each cubic centimeter not more than 4 rat units of ovarian extract. It was alleged to be misbranded in that the statement on the label, "Ovarian Extract * * * 50 Rat Units per cc." was false and misleading.

On April 20, 1942, a plea of nolo contendere having been entered on behalf of the defendant, the court imposed a fine of $75 on four of the counts, i. e., a total of $300; and ordered that imposition of sentence on the remaining counts be suspended for 1 year, that the defendant be placed on probation for 1 year, and that if no further violation occurred no further penalties be imposed.

757. Misbranding of Nomo For Piles, Sanafrio, and Asmolac. U. S. v. Albert B. Hirschman (Hirschman Laboratories and Sanafrio Laboratories). Plea of nolo contendere. Fine, $75 on each of 3 counts; sentence suspended on all but first count. (F. D. C. No. 5491. Sample Nos. 26467–E, 26469–E, 32632–E.)

The labeling of the Asmolac failed to bear adequate directions for use, such adequate warnings as are necessary for the protection of users, and a declaration of the alkaloids of atropine, hyoscine, and hyoscyamine that were present. The labeling of all three products bore false and misleading curative and therapeutic claims.

On November 3, 1941, the United States attorney for the Southern District of California filed an information against Albert B. Hirschman, trading as Hirschman Laboratories and as Sanafrio Laboratories, San Pedro, Calif., alleging shipment within the period from on or about May 14 to on or about July 1, 1940, from the State of California into the States of Arizona and Oregon of quantities of the above-named drugs which were misbranded.

Analyses of samples showed that the Asmolac consisted essentially of water, alcohol, plant extractives, alkaloids, reducing sugars, potassium iodide, and sodium iodide; that the Sanafrio consisted essentially of fat, zinc oxide, camphor, and menthol; and that the Nomo For Piles consisted essentially of benzocaine, boric acid, eucalyptus oil, fixed oils, and zinc oxide.

The Asmolac was alleged to be misbranded: (1) In that the directions for use contained no limitation as to duration of administration. (2) In that it contained (a) iodine or iodides and the labeling failed to warn that it should not be used in case of goiter except upon the advice of a physician and should be discontinued if skin rash appears; and (b) the alkaloids of belladonna and hyoscyamus and the labeling failed to warn that frequent or continued use should be avoided, that it should be used cautiously if dryness of the throat occurs, that it should be discontinued if rapid pulse or blurring of the vision occurs, and that it should not be taken by elderly people except upon competent advice. (3) In that the name "Asmolac" and the statements in the accompanying circular, "Where it is not deemed necessary to use Asmolac continuously, you should watch for the approaching of attacks such as nervousness, headache, itching of the nose or skin, severe sneezing, yawning, and other suggestive symptoms. If this is noticeable take half a teaspoon of Asmolac twice a day. In this way the actual spasms are usually to the greatest extent and often completely prevented," were false and misleading since they represented that when used as directed in the above-named conditions, it often would completely prevent the actual spasms of asthma; whereas if used as directed, it would not often, nor at all, completely prevent the actual spasms of asthma. (4) In that it contained the alkaloids of atropine, hyoscine, and hyoscyamine, but the labeling did not contain the name and quantity or proportion of said alkaloids or, in lieu thereof, the quantity or proportion of total alkaloids of belladonna and hyoscyamus that it contained.

The Nomo For Piles was alleged to be misbranded: (1) In that the name "Nomo For Piles" and the statements in the labeling, (carton only) "Astringent," (carton, tube, and circular) "To Relieve * * * Soreness * * * Associated with Piles," and (circular) "For the relief of pain it is highly recommended," were false and misleading since they represented and suggested that it was a competent treatment for all cases of piles and would be efficacious to relieve the soreness and pain associated with piles; whereas it would not accomplish such results. (2) In that the labeling was misleading since it failed to reveal the fact, material in the light of the representations which it contained, that the preparation did not constitute a treatment for all kinds of piles and that competent advice should be secured in cases of excessive bleeding.

The Sanafrio was alleged to be misbranded in that the following statements in the labeling, (carton) "For * * * Chest Colds * * * Relieves Headache, Neuralgia, Inflammation in Head Colds, and similar conditions. * * * Directions Apply externally to the chest. Acts much like a plaster and helps to relieve local congestion," and (jar) "Relieves Headache, Neuralgia, Congestion, and Inflammation in * * * Chest Colds and similar conditions * * * Chest Colds, Cough, Sore Throat," were false and misleading since it would not be efficacious as a treatment or relief for such conditions.

On May 19, 1942, the defendant having entered a plea of nolo contendere, the court imposed a fine of $75 on each of the 3 counts and suspended the sentence on counts 2 and 3 on condition that the defendant comply with instructions of the Government.

758. Misbranding of agar and oil with phenolphthalein. U. S. v. 28 Dozen Bottles of Royale Agar and Oil (and 1 other seizure action against Agar and Oil with Phenolphthalein). Default decrees of condemnation and destruction. (F. D. C. Nos. 7052, 7647. Sample Nos. 40894–E, 77140–E.)

The bottles containing this product were unlabeled when shipped in interstate commerce.

On March 18, and June 15, 1942, the United States attorney for the Eastern District of Pennsylvania filed libels against 61 dozen bottles of Agar and Oil with Phenolphthalein at Philadelphia, Pa., alleging that the article had been shipped in interstate commerce on or about January 7 and March 21, 1942, by the Vital Laboratories from Union City, N. J.; and charging that is was misbranded. After shipment a portion of the article was labeled in part, (bottle) "Royale Agar and Oil with Phenolphthalein"; and the cartons containing the remainder were labeled in part, "I. S. 137 1 Doz 16 Oz."

Analysis showed that the article was an emulsion containing mineral oil and phenolphthalein.

It was alleged to be misbranded in that it bore no labeling containing (1) adequate directions for use; (2) adequate warnings, since the label failed to warn that it should not be taken when suffering from nausea, vomiting, abdominal pain, or other symptoms of appendicitis, and that frequent or continued use might result in dependence upon laxatives; (3) the name and place of business of the manufacturer, packer, or distributor; (4) an accurate statement of the quantity of the contents; and (5) the common or usual name of each active ingredient.

On May 1 and July 6, 1942, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

759. Adulteration and misbranding of Aurofectol; misbranding of Purpoil No. 22 and Purpoil No. 600. U. S. v. 6⅔ Dozen Packages of Purpoil No. 22, 3½ Dozen Packages of Purpoil No. 600, and 2½ Dozen Packages of Aurofectol. Default decree of condemnation and destruction. (F. D. C. No. 7474. Sample Nos. 87163–E, to 87165–E., incl.)

The labeling of the Purpoil Nos. 22 and 600 failed to bear such warnings as are necessary for the protection of users and also contained false and misleading curative and therapeutic claims. The labeling of the Aurofectol contained false and misleading claims regarding its curative, therapeutic, and antiseptic properties.

On May 6, 1942, the United States attorney for the District of Columbia filed a libel against the above-named products at Washington, D. C., alleging that they had been shipped in interstate commerce on or about March 9 and 25, 1942, by Purpoil Laboratories, Inc., from Baltimore, Md.; and charging that they were misbranded and that the Aurofectol was also adulterated.

Analyses of samples of the Purpoil Nos. 22 and 600 showed that both consisted essentially of mineral oil containing small quantities of iodine, chlorobutanol, and menthol. Analysis of a sample of the Aurofectol showed that it consisted essentially of a mixture of oils and phenols. Bacteriological tests of the Aurofectol showed that it was not antiseptic.

The Purpoil Nos. 22 and 600 were alleged to be misbranded in that their labels failed to bear adequate warnings against use by children where their use might be dangerous to health and failed to bear adequate warnings against unsafe duration of administration or application in such manner and form as are necessary for the protection of users, since they failed to warn that use by children might be dangerous and that frequent or excessive use might cause injury to the lungs. The Purpoil No. 22 was alleged to be misbranded further

(1) in that statements in the labeling which represented and suggested that it would be efficacious in the treatment of acute and mild chronic infections of the nose, that it would cause a depletion of the swollen mucous membrane, would promote drainage and greatly improve ventilation, would be efficacious to promote healing and would gradually diminish excess discharge, whether due to acute coryza or chronic nasal infection and whether the discharge was purulent or mucopurulent in quality, and would be equally efficient or effective whether dealing with repulsive scab formation or ozena or persistent postnasal drip, were false and misleading since it would not be efficacious for such purposes; (2) in that the following statement in the labeling, "Bacteriological tests have shown that Purpoil No. 22 and Purpoil No. 600 have bacteria destroying properties which are equivalent to phenol in the same strength and in the same type of oil," was false and misleading since it failed to reveal the material fact that phenol in the same strength and in the same type of oil possesses no bacteria-destroying properties. The Purpoil No. 600 was alleged to be misbranded further in that the statement "Used in the treatment of chronic suppurative infections of the nose" was false and misleading since it would not be efficacious in the treatment of suppurative infections of the nose.

The Aurofectol was alleged to be adulterated in that its strength differed from that which it was represented to possess since it was not an antiseptic as represented in its labeling. It was alleged to be misbranded in that certain statements in the labeling which represented that it would be efficacious in the treatment of dermatitis, eczema, and acute catarrhal inflammation of the tympanic membrane; would be efficacious in the treatment of acute and chronic infections of the external auditory canal and acute myringitis and acute catarrhal otitis media; that it was an effective parasiticide and antiseptic in skin diseases; that it would produce desired results in external auditory canal infections; that it would be efficacious in the treatment of infections of the skin of the external auditory canal were false and misleading since it would not be efficacious for such purposes.

On June 11, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

760. Misbranding of Fermlax. U. S. v. 61 Packages of Fermlax. Default decree of condemnation and destruction. (F. D. C. No. 7450. Sample No. 70672–E.)

On May 5, 1942, the United States attorney for the Eastern District of Tennessee filed a libel against 61 packages of Fermlax at Chattanooga, Tenn., alleging that the article had been shipped in interstate commerce on or about March 11, 1942, by Moon-Winn Drug Co., Inc., from Athens, Ga.; and charging that it was misbranded.

Analysis of a sample of the article showed that it consisted essentially of sodium bicarbonate, magnesium carbonate, calcium carbonate, bismuth subnitrate, and rhubarb.

The article was alleged to be misbranded: (1) In that the directions on the label, "Adult dose—Teaspoonful in a full glass of water three times a day after meals. Children in proportion to age," provided for continuous administration, whereas it was a laxative and should not be used continuously, and they also failed to indicate the dosage for children of different ages. (2) In that the labeling failed to warn that a laxative should not be used in case of nausea, vomiting, abdominal pain, or other symptoms of appendicitis; and that frequent or continued use of a laxative might result in dependence upon a laxative to move the bowels. (3) In that it was in package form and its label failed to bear an accurate statement of the quantity of the contents.

On June 12, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

761. Misbranding of laxative cold tablets and Rx S368230 Pills. Adulteration and misbranding of epinephrine tablets for hypodermic use. U. S. v. 84 Bottles of Laxative Cold Tablets, 14,800 Rx S368230 Pills, and 2,045 Tubes and 6,040 Packages of Hypodermic Tablets. Default decrees ordering destruction of laxative cold tablets, pills, and portion of hypodermic tablets. Consent decree of condemnation ordering portion of hypodermic tablets released under bond to be brought into compliance with the law. (F. D. C. Nos. 7324, 7480, 8271, 8331. Sample Nos. 76829–E, 91224–E, 91225–E, 4959–F, 5078–F.)

The labeling of the laxative cold tablets and of the Rx S368230 Pills (a portion of which had been repackaged and labeled in part, "Gloria Laxative Pills * * * Prepared for John A. Smith Co., Oconomowoc, Wis.") failed to bear adequate directions and warning statements, that of the pills also failed

to bear a satisfactory statement of the active ingredients, and that of the laxative cold tablets and the hypodermic tablets also bore false and misleading statements. The epinephrine hypodermic tablets contained only three-fourths as much epinephrine as the amount declared on the label.

On April 30, May 8, August 29, and September 8, 1942, the United States attorneys for the Northern District of Illinois, Eastern District of Wisconsin, and the Northern and Southern Districts of Ohio filed libels against 49 bottles each containing 100, and 35 bottles each containing 1,000 laxative cold tablets at Chicago, Ill.; 14,800 Rx S368230 Pills at Oconomowoc, Wis.; 6,040 packages each containing 100 epinephrine tablets at Columbus, Ohio; and 2,045 tubes each containing 20 epinephrine tablets at Toledo, Ohio, alleging that the articles had been shipped in interstate commerce within the period from on or about January 13, 1941, to on or about July 14, 1942, by Parke, Davis & Co. from Detroit, Mich.; and charging that the cold tablets and pills were misbranded, and that the epinephrine tablets were adulterated and misbranded.

Analyses of samples showed that the laxative cold tablets each contained approximately 2 grains of acetanilid, plant extractives (including resinous material), a quinine compound, and caffeine; and that the pills contained aloin and an extract of cascara sagrada.

The laxative cold tablets were alleged to be misbranded: (1) In that the labeling failed to bear adequate directions for use since it contained no directions as to frequency or duration of administration. (2) In that the labeling failed to bear adequate warnings since (a) they contained acetanilid and it did not warn that frequent or continued use might therefore be dangerous, causing serious blood disturbances, anemia, collapse, or a dependence upon acetanilid, and that they should not be given to children; and (b) they contained laxative ingredients and the label did not warn against their use in case of abdominal pain and nausea, vomiting, or other symptoms of appendicitis; or that frequent or continued use might result in dependence upon laxatives to move the bowels. (3) In that the statement on the label, "Cold * * * (Grip)," was false and misleading since they did not constitute an adequate treatment for cold or grippe.

The pills were alleged to be misbranded: (1) In that the labeling failed to bear any directions for their use. (2) In that the labeling failed to warn that they were not to be used in the presence of abdominal pain, nausea, vomiting, or other symptoms of appendicitis; and that frequent or continued use might result in dependence upon laxatives. (3) In that the label failed to bear the common or usual names of the active ingredients since "Cascarin Bitter" is not the common or usual name of any substance.

The epinephrine tablets were alleged to be adulterated in that their strength differed from that which they purported and were represented to possess, namely, (label) "Tablets Epinephrine 3/200 grain" and "One tablet dissolved in 1cc. of water makes a 0.1% solution," since each tablet contained less than 3/200 grain of epinephrine and 1 tablet dissolved in 1 cc. of water would make a solution of less concentration than 0.1 percent of epinephrine. They were alleged to be misbranded in that the above-quoted statements were false and misleading.

One June 1, August 26, and November 9, 1942, no claimant having appeared for the seizures at Chicago, Oconomowoc, and Columbus, judgments were entered ordering that they be destroyed. On February 6, 1943, Parke, Davis & Co., claimant for the seizure at Toledo, having admitted the material allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond conditioned that it be brought into compliance with the law under the supervision of the Food and Drug Administration.

762. Adulteration and misbranding of Gloria Tonic tablets. U. S. v. 74 Packages of Gloria Tonic. Default decree of condemnation and destruction. (F. D. C. No. 7338. Sample No. 80185–E.)

On April 16, 1942, the United States attorney for the Northern District of Ohio filed a libel against 74 packages of Gloria Tonic tablets at Cleveland, Ohio, alleging that the article had been shipped in interstate commerce on or about October 20, 1941, by the John A. Smith Co. from Oconomowoc, Wis.; and charging that it was adulterated and misbranded.

Analysis showed that the tablets contained iron (0.77 grain), sodium salicylate (3.64 grains), colchicine (0.003 grain), and extract of cascara sagrada.

The article was alleged to be adulterated in that its strength differed from that which it purported or was represented to possess, namely, "Each tablet contains reduced Iron 1 gr., * * * Sodium Salicylate 5 gr., Colchicine 1–250 gr."

It was alleged to be misbranded: (1) In that the labeling failed to bear adequate directions for use since those which appeared on the label did not provide for sufficient medication to constitute a treatment for gout. (2) In that [its labeling failed to bear adequate warnings] since it was a laxative and the label failed to warn that it should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis were present, and that frequent or continued use might result in dependence upon laxatives. (3) In that the statement "Tonic * * * An Allevial Treatment Useful in * * * Gout" was false and misleading since the tablets when used as directed did not constitute a tonic or treatment for gout.

On June 26, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

763. Misbranding of solution of citrate of magnesia. U. S. v. 144 Bottles of Solution Citrate of Magnesia U. S. P. Default decree of condemnation and destruction. (F. D. C. No. 7397. Sample No. 79270–E.)

On April 27, 1942, the United States attorney for the Southern District of Indiana filed a libel against the above-named product at Richmond, Ind., alleging that it had been shipped in interstate commerce on or about January 26, 1942, by Gordon Pharmacal Co. from Cincinnati, Ohio; and charging that it was misbranded in that it was a laxative and its labeling failed to warn that a laxative should not be taken in case of nausea, vomiting, abdominal pain, or other symptoms of appendicitis, and that frequent or continued use of a laxative might result in dependence upon laxatives to move the bowels.

On June 4, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

764. Misbranding of Pond's Digestans and Pond's Laxative Pills. U. S. v. 12 Dozen, 4 Dozen, and 1 Dozen Tins of Pond's Digestans. Default decree of condemnation and destruction. (F. D. C. No. 6588. Sample No. 74170–E.)

The labeling of these products failed to bear adequate directions for use and such adequate warnings as are necessary for the protection of users, and did bear false and misleading therapeutic claims. The labeling also failed to state the common or usual names of the active ingredients of the laxative pills.

On December 19, 1941, the United States attorney for the District of New Jersey filed a libel against 12 dozen 15-cent, 4 dozen 35-cent, and 1 dozen 65-cent-sized tins of Pond's Digestans, each tin containing a number of brown-coated tablets and a small envelope containing 3 pink pills, labeled "Pond's Laxative Pills," at Newark, N. J., alleging that the articles had been shipped in interstate commerce on or about October 8 and November 13, 1941, by Pond Pharmacal Co., Inc., from New York, N. Y.; and charging that they were misbranded.

Analyses of samples showed that Pond's Digestans tablets consisted essentially of sodium bicarbonate, extracts of laxative plant drugs (including aloin), peppermint oil, and strychnine sulfate; and that the laxative pills consisted essentially of laxative plant drugs (including aloin and podophyllin), and small quantities of belladonna.

The articles were alleged to be misbranded: (1) In that the directions for use appearing on the tins and in the circulars were inappropriate and inadequate for a laxative since they provided for continued administration, which might result in dependence upon a laxative. (2) In that although the labeling cautioned the user against the use of laxatives in the presence of nausea, vomiting, and abdominal pain, it failed to warn that such symptoms may be those of appendicitis; and the tablets contained strychnine but the labeling failed to warn that not more than the recommended dosage should be taken and that its use by children and elderly persons might be especially dangerous. (3) In that the warnings required by law had not been placed upon the labeling with such conspicuousness as compared with other words and statements as to render them likely to be read or understood by the ordinary individual under customary conditions of purchase and use since the warning that did appear was in very small type and at the bottom of the first page of the circular enclosed in the tin. (4) In that the following statements in the labeling, "Digestans * * * These tablets * * * have been found of great value * * * in relieving * * * wind colic. * * * contain bitter stomach tonics used to stimulate the flow of gastric juices. * * * Oil of Peppermint is * * * stimulant to the appetite * * * Gentian is a stimulant to the appetite and is the most popular of all the bitters for its stomachic action. Ipecac in small doses is a carminative, stimulates the appetite and helps the action of the other ingredients. * * * Rhubarb is also a widely prescribed remedy as a * * * bitter," were false and misleading since the name "Digestans" created the impression

that the article so designated was a digestant of food, and the statements created the impression that Digestans would relieve wind colic, that it contained bitter stomach tonics which would stimulate the flow of gastric juices and that the ingredients named would accomplish the individual effects claimed for them; whereas Digestans was not a digestant of food, it would not relieve wind colic, it did not contain bitter stomach tonics that would stimulate the flow of gastric juices, and it would not accomplish the results attributed individually to oil of peppermint, gentian, ipecac, and rhubarb. (5) In that the outside container did not bear an accurate statement of the quantity of the contents with respect to Pond's Laxative Pills. (6) In that the tin and glassine envelope did not bear the common or usual names of the active ingredients of Pond's Laxative Pills.

On May 8, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

765. Misbranding of My-X-Ym. U. S. v. 28 Packages of My-X-Ym. Default decree of condemnation and destruction. (F. D. C. No. 7380. Sample No. 23391-E.)

On April 27, 1942, the United States attorney for the Northern District of California filed a libel against 28 packages of My-X-Ym at Salinas, Calif., alleging that the article had been shipped in interstate commerce on or about March 2, 1942, by My-X-Ym Food Enzymes Products from Chicago, Ill.; and charging that it was misbranded.

Analyses of samples of the article showed that it consisted essentially of ground senna pods, powdered milk, yeast, wheat bran, cornstarch, cacao powder, soybean tissues, and sugars including dextrose and sucrose.

The article was alleged to be misbranded: (1) In that its labeling failed to bear adequate warnings since it was a laxative and the label failed to warn that a laxative should not be taken in cases of nausea, vomiting, abdominal pain, or other symptoms of appendicitis; and that frequent or continued use of a laxative may result in dependence upon a laxative to move the bowels. (2) In that the directions which appeared in the labeling provided for continuous administration whereas a laxative should not be used continuously. (3) In that statements in the labeling which represented and suggested that it was an enzyme product and that when used as directed, it would balance the weight of the body, would be efficacious "for health," would supply a factor the absence of which causes many ailments to develop; would cause the glandular system to function properly and would restore energy and vigor; would prevent bacteria from forming toxic matter in the gastro-intestinal tract and would detoxify the system; that it was an adequate treatment for chronic angioneurotic edema, allergic eczema, pancreatic indigestion, allergic rhinitis, chronic allergic headache, allergic vomiting, chronic urticaria, allergic edema, allergic papular eczema, chronic allergic colitis, gastric and pancreatic achylia, acidosis, autointoxication, acne, appendicitis, bad breath, constipation, colitis, colds, catarrhal disease, gall bladder trouble, headache, neuritis, underweight, obesity, piles, rheumatism, stomach disorders, sluggishness, and spasmatic colon; that it was a preventive of catarrhal conditions of the sinuses, nose, ears, throat, bronchial tubes, lungs, stomach, liver, gall bladder, pancreas, intestines and colon, were false and misleading since it was not an enzyme product and would not be effective for the above-named diseases, symptoms, and conditions.

On June 18, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS [4]

DRUGS FOR HUMAN USE

766. Adulteration and misbranding of Adiron tablets; misbranding of Floramucin. U. S. v. Lawrence M. Williams (Lawrence Laboratories). Plea of guilty. Fine, $250 and costs. (F. D. C. No. 5531. Sample Nos. 60557-E to 60560-E, incl.)

The Adiron tablets were deficient in vitamins A and D, and the labeling of Floramucin bore false and misleading statements.

On February 27, 1942, the United States attorney for the Northern District of Illinois filed an information against Lawrence M. Williams, trading as Lawrence Laboratories at Chicago, Ill., alleging shipment in interstate commerce within the

[4] See also Nos. 755, 756, 759, 762.

period from on or about January 27 to on or about March 7, 1941, from the State of Illinois into the State of Washington of quantities of Floramucin which was misbranded, and of a quantity of Adiron which was adulterated and misbranded.

The Adiron was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and was represented to possess since it was represented to contain in each tablet, 1,200 U. S. P. XI units of vitamin A and 180 U. S. P. XI units of vitamin D, but did contain not more than 300 U. S. P. XI units of vitamin A and not more than 100 U. S. P. XI units of vitamin D. It was alleged to be misbranded in that the statement on the label, "Adiron * * * Tablets, each contain * * * 1200 U. S. P. XI Units Vitamin 'A' 180 U. S. P. XI Units Vitamin 'D', " was false and misleading.

The information alleged that the Adiron was also adulterated and misbranded under the provisions of the law applicable to foods, as reported in F. N. J. No. 3838.

Analysis of a sample of Floramucin showed that it consisted essentially of the mucilaginous portion of psyllium seed, karaya gum, sugar, and dextrin.

Floramucin was alleged to be misbranded: (1) In that the statement (display card) "Detoxification aids in getting rid of the poisons," and those in an accompanying circular which represented and suggested that it would detoxify and aid in getting rid of poisons; that it would be efficacious in the treatment of biliousness, sore stomach, indigestion, intestinal stasis, excess gas, colitis, torpid liver, and stomach and intestinal troubles; that it would combat constipation and colitis without laxatives, implying that it was not a laxative; that it would keep the digestive tract vigorous and healthy and would restore it to vigor and health if it were impaired; that it would be efficacious to insure quick and effective relief from faulty elimination; would soothe and ease sore, inflamed, and irritated conditions of the intestinal lining and assist natural healing processes; would infiltrate into every wrinkle and fold of each pocket of the intestines and make movement of the entire mass of the feces more easy and aid by its bulk in setting up normal peristalsis; would detoxify by better elimination of stagnant and putrefactive matter and would induce complete evacuation without irritating laxatives; would aid in combating auto-intoxication and resulting self-poisoning and would help break the laxative habit; would enable the consumer to reduce the quantity of laxatives and cathartics used and finally eliminate the necessity for using it, were false and misleading since it would not be efficacious for such purposes. (2) In that the statements, "with dextrine for its well-known flora-changing properties in encouraging the growth of B. Acidophilus and similar friendly organisms in the colon," "Dosage varies from 2 to 5 teaspoonfuls daily," "An adjuvant Food—Not a Drug," "Without Laxatives," "A Mucin—Not a Gum The earlier attempts to aid nature in this direction were mere gums like Karaya, * * * Bulk—but nothing else," were false and misleading since they represented that in the dosage recommended, it would be efficacious in changing the flora in the intestines and encouraging the growth of *B. acidophilus* and similar friendly organisms; that it was not a drug nor a laxative; and that it did not contain a gum and was more than a bulk-producing laxative, but it would not be efficacious in changing the flora in the intestines or encouraging the growth of *B. acidophilus*, it did contain the mucilaginous part of psyllium seed and karaya gum, which are laxative drugs, and it was a bulk-producing laxative. (3) In that the statement of the active ingredients, "Hexose Mucinoid fraction of Plantago Ovata (East Indian psyllium) Dextrine, Karaya Gum and Raw Sugar," required by the law to appear on the label, was not prominently placed thereon in such terms as to render it likely to be understood by the ordinary individual under customary conditions of purchase and use, since the expression "Hexose Mucinoid fraction of Plantago Ovata (East Indian psyllium)" was not the common name of one of the ingredients, i. e., the mucilaginous part of psyllium seed; dextrin and raw sugar were not active ingredients as implied in said statement, and the statement of ingredients did not distinguish between its active and nonactive constituents.

On March 3, 1942, a plea of guilty was entered to all charges and the court imposed a fine of $250, which covered all counts of the information.

767. Adulteration and misbranding of thyroid powder. U. S. v. Martha E. Johnston (H. H. Johnston Laboratories) and Arthur V. Jones. Pleas of nolo contendere. Total net fines, $40; each defendant fined $100 of which $80 was suspended. (F. D. C. No. 6502. Sample No. 65865-E.)

On June 11, 1942, the United States attorney for the Southern District of California filed an information against Martha E. Johnston, trading as H. H. Johnston Laboratories at Hollywood, Calif., and Arthur V. Jones, manufacturing pharmacist and salesman for H. H. Johnston Laboratories, alleging shipment

on or about August 18, 1941, from the State of California into the State of Colorado of a quantity of thyroid powder which was adulterated and misbranded.

The article was alleged to be adulterated in that it purported to be and was represented as a drug the name of which, i. e., thyroid, is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from and its quality fell below the standard set forth therein since the pharmacopoeia provides that thyroid contain not less than 0.17 percent of iodine in thyroid combination; whereas it contained not more than 0.134 percent of iodine in thyroid combination, and its difference in strength and quality from such standard was not plainly stated on the label. It was alleged to be misbranded in that the statement on the bottle label, "Thyroid Powder U. S. P. XI," was false and misleading.

On June 26, 1942, the defendants entered pleas of nolo contendere, and the court imposed fines of $100 against each defendant but suspended payment of $80 of each of the fines, thus reducing the total amount of the fines paid to $40.

768. Adulteration of powdered borax. U. S. v. 1 Barrel and 2 Barrels of Powdered Borax. Default decree of condemnation and destruction. (F. D. C. Nos. 7495, 7496. Sample Nos. 59785–E, 87584–E.)

Samples taken from this product were found to contain 3.4, 3.8, and 3.9 parts, respectively, of arsenic trioxide in each 100,000 parts of borax; whereas the U. S. Pharmacopoeia provides that it should contain not more than 1 part of arsenic trioxide per 100,000 parts.

On May 20, 1942, the United States attorney for the District of Maryland filed libels against 3 barrels, each containing 300 pounds of powdered borax at Baltimore, Md., alleging that the article had been shipped in interstate commerce on or about February 21, 1942, by the American Potash & Chemical Corporation from Trona, Calif.; and charging that it was adulterated in that it purported to be a drug the name of which is recognized in the U. S. Pharmacopoeia but its purity fell below the standard set forth in that compendium and its difference in purity from such standard was not stated on its label.

On June 24, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

769. Adulteration and misbranding of chorionic gonadotropic hormone. U. S. v. 12 Vials of Chorionic Gonadotropic Hormone. Default decree of condemnation and destruction. (F. D. C. No. 7845. Sample No. 77049–E.)

On July 1, 1942, the United States attorney for the Eastern District of Pennsylvania filed a libel against the above-named product at Philadelphia, Pa., alleging that it had been shipped in interstate commerce on or about May 27, 1942, by the Pro-Medico Laboratories, Inc., from Brooklyn, N. Y.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that its strength differed from that which it purported and was represented to possess, namely, (label) "Anterior pituitary-like sex hormone standardized to a potency of 500 International units per cc. * * * 5000 International units of Chorionic Gonadotropic Hormone per 10 cc." since its potency was less than 835 International Units per 10 cc.

It was alleged to be misbranded in that the statements, "10 cc. * * * Package 5000 International Units * * * Chorionic Gonadotropic Hormone," and "Contains Anterior pituitary-like sex hormone standardized to a potency of 500 International units per cc." were false and misleading since they represented and suggested that it had a potency of 500 International Units of chorionic gonadotropic hormone per cc.; whereas it had a potency of less than 500 International Units per cc.

On July 17, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

770. Adulteration and misbranding of Effervescing Solution of Citrate of Magnesia with Magnesia Sulphate. U. S. v. 342 Bottles of Effervescing Solution of Citrate of Magnesia with Magnesia Sulphate. Default decree of condemnation and destruction. (F. D. C. No. 6758. Sample No. 90417–E.)

This product was labeled to indicate that it consisted of a standard solution of citrate of magnesia to which magnesium sulfate (Epsom salt) had been added; but it actually contained only about one-fourth as much magnesium oxide and one-seventh as much citric acid as required by the U. S. Pharmacopoeial standard. Furthermore, it contained Epsom salt in such an amount (approximately 10 grains per recommended dose of 11 fluid ounces) that its purgative effect was due primarily to the added Epsom salt.

On February 4, 1942, the United States attorney for the District of Rhode Island filed a libel against the above-named product at Providence, R. I., alleging that it had been shipped in interstate commerce on or about September 11, 1941, by Roma Extract Co., Inc., from Boston, Mass.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that its strength differed from that which it purported and was represented to possess, namely, "Effervescing Solution of Citrate of Magnesia with Magnesia Sulphate," since its strength differed from that of a solution of magnesium citrate to which magnesium sulfate had been added. It was alleged to be misbranded in that the title, "Effervescing Solution of Citrate of Magnesia with Magnesia Sulphate," borne on the label, was false and misleading.

On April 1, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

771. Adulteration of Nebulin A with Nebulator. U. S. v. 141 Packages of Nebulin A with Nebulator. Default decree of condemnation and destruction. (F. D. C. No. 7477. Sample No. 73653–E.)

On May 11, 1942, the United States attorney for the Western District of Missouri filed a libel against 141 packages of Nebulin A with Nebulator at Kansas City, Mo., alleging that the article had been shipped in interstate commerce within the period from on or about February 6, to on or about April 10, 1942, by the Nyal Co. from Detroit, Mich.; and charging that it was adulterated. The article was labeled in part: (Package) "Combination package consisting of Nebulin A with Nebulator * * * Frederick Stearns & Company Detroit, U. S. A."; (bottle contained in package) "Nebulin A Stearns Solution Epinephrine Hydrochloride 1:100 Contains: * * * 1.0% * * * in an aqueous vehicle."

It was alleged to be adulterated in that it was represented as a drug the name of which is recognized in the United States Pharmacopoeia but its quality fell below and its strength differed from the standard set forth in that compendium, since it was a brown liquid and the pharmacopoeia specifies that epinephrine hydrochloride is "a nearly colorless * * * liquid * * * when the solution has become brown in color * * * it must be rejected," and its strength was five times that specified in the pharmacopoeia and its difference in strength and quality from such standard was not stated on the label.

On June 16, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

772. Adulteration and misbranding of Ramsdell's Sulphur Cream. U. S. v. 129 Packages of Ramsdell's Sulphur Cream. Default decree of condemnation and destruction. (F. D. C. No. 7499. Sample No. 84378–E.)

This product, in addition to containing a smaller amount of sulfur than that declared, bore false and misleading therapeutic claims in the labeling.

On May 15, 1942, the United States attorney for the District of New Jersey filed a libel against 129 packages of Ramsdell's Sulphur Cream at Newark, N. J., alleging that the article had been shipped in interstate commerce on or about April 22, 1942, by E. Fougera & Co., Inc., from New York, N. Y.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that its strength differed from that which it purported or was represented to possess, namely, "Contains 10% Precipitated Sulphur."

It was alleged to be misbranded in that certain statements in the labeling, which represented that it would be efficacious in the treatment of scabies, eczema, ringworm, itching, simple acne, acne rosacea, burning and soreness in eczema, "Jock-Strop itch," barber's itch, and water rash; and that it would be efficacious in the treatment of bald spots and falling hair, were false and misleading since it would not be efficacious for such purposes.

On July 7, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

773. Adulteration and misbranding of Blue Fin Tuna Liver Oil. U. S. v. 1 Drum of Blue Fin Tuna Liver Oil. Decree of condemnation. Product released under bond for relabeling. (F. D. C. No. 1858. Sample No. 55486–D.)

This product contained a smaller amount of vitamin D than that declared on the label.

On April 22, 1940, the United States attorney for the Eastern District of Michigan filed a libel against 1 drum of the above-named product at Detroit,

Mich., alleging that it had been shipped in interstate commerce on or about July 14, 1939, by S. B. Penick & Co. from Jersey City, N. J.; and charging that it was adulterated and misbranded. Two drums of oil having been seized, one of which was not in violation of the law, an order was entered on June 14, 1940, releasing the drum which had been erroneously seized.

The article was alleged to be adulterated in that its strength differed from and its purity fell below that which it purported or was represented to possess.

It was alleged to be misbranded in that the statement "35,000 U. S. P. Units of Vitamin D per gram," stenciled on the drum, was false and misleading, since it did not contain 35,000 U. S. P. units of vitamin D per gram.

On July 29, 1940, S. B. Penick & Co., claimant, filed a motion for discovery of the Government's assay and on July 31 an order was entered directing that, upon the claimant's filing its answer, the Government produce and permit the inspection and copying of documents which showed the results of the assay or assays.

On February 28, 1941, the claimant having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond conditioned that it be relabeled under the supervision of the Food and Drug Administration as follows: "Blue Fin Tuna Liver Oil 100,000 U. S. P. Units of Vitamin A Per Gram, 20,000 U. S. P. Units of Vitamin D Per Gram."

774. Adulteration and misbranding of Vi-Penta Drops 'Roche'. U. S. v. 234 Vials of Vi-Penta Drops 'Roche'. Default decree of condemnation and destruction. (F. D. C. No. 4833. Sample No. 69145–E.)

This product was represented to contain 9,000 U. S. P. units of vitamin A per 0.6 cc. but in fact contained not more than 3,500 U. S. P. units of vitamin A per 0.6 cc.

On May 27, 1941, the United States attorney for the Southern District of New York filed a libel (amended September 16, 1941) against the above-named product at New York, N. Y., alleging that it had been shipped in interstate commerce on or about April 22, 1941, by Hoffman-La Roche, Inc., from Nutley, N. J.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it was represented to possess, namely, 9,000 U. S. P. units of vitamin A per 0.6 cc., since it contained much less than 9,000 U. S. P. units of vitamin A per 0.6 cc.

It was alleged to be misbranded in that the statements, (circular) "Each 10-minim dose of Vi-Penta Drops contains: Vitamin A 9000 U. S. P. Units * * * Indications for Vi-Penta Drops * * * For the normal growth and development of infants or children. In cases of malnutrition, lowered resistance or run-down states. During prolonged illness such as infections, anemias, tuberculosis, typhoid, etc. * * * For gastrointestinal conditions, such as diarrhea, colitis, etc. When restrictions in diet are necessary, as in obesity, diabetes, catarrhal jaundice, etc. Whenever the total food intake must be increased, as in hyperthyroid conditions. For the treatment of certain skin diseases, such as eczema. In certain allergic conditions, such as those due to milk, eggs, wheat, etc. During periods of temporary or persistent vomiting (in infancy, childhood, or pregnancy). In the prophylaxis or treatment of abnormal dentition (or gum and tooth conditions)," were false and misleading since it would not be efficacious for such purposes.

It was also alleged to be adulterated and misbranded under the provisions of the law applicable to food, as reported in notices of judgment on foods.

On March 17, 1942, Hoffman-La Roche, Inc., claimant, having consented to the entry of the decree, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS FOR VETERINARY USE

775. Adulteration and misbranding of sodium cacodylate solution, alkaline compound powder, calcium gluconate compound solution, diuretic powder, canine worm tablets, liquid nux vomica alkaloids, and tonic powder; and misbranding of Arsenol Compound Powder, glucose solution, potassium arsenite compound tablets, santonin-calomel tablets, Guaiadine Tablets, Conjunctivities #1 Tablets, and tetrachlorethylene capsules. U. S. v. Peerless Serum Co. Plea of guilty. Fine, $105 and costs. (F. D. C. No. 555. Sample Nos. 43057–E to 43059–E, incl., 43061–E, 43063–E to 43065–E, incl., 43067–E, 43069–E, 43074–E to 43076–E, incl., 43078–E, 43079–E.)

The labeling of these veterinary preparations, with the exception of the potassium arsenite compound tablets, and the liquid nux vomica alkaloids, bore

false and misleading curative claims. Some of the products fell below their own declared standards and others failed to comply with certain labeling requirements of the law.

On March 28, 1942, the United States attorney for the District of Kansas filed an information against the Peerless Serum Co., a corporation having a place of business at Kansas City, Kans., alleging shipment within the period from on or about August 16 to on or about October 25, 1940, from the State of Kansas into the State of Oklahoma of quantities of the above-named veterinary preparations which were misbranded and some of which were also adulterated.

Analysis of the sodium cacodylate solution showed that it contained not more than 2.53 grains of sodium cacodylate per cc. It was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and was represented to possess, since it was represented to contain 4.5 grains of sodium cacodylate per cc.; whereas it contained not more than 2.53 grains of sodium cacodylate per cc. It was alleged to be misbranded (1) in that the statement on the bottle label, "Sodium Cacodylate Solution 4.5 Gr. per cc." was false and misleading; (2) in that the statements on the bottle label, "Useful in the treatment of Anaplasmosis, Swamp Fever, Anemia, Influenza, Shipping Fever, Chronic Skin Diseases and to build up Convalescent Patients," were false and misleading since it would not be efficacious for such purposes; and (3) in that it contained sodium cacodylate, a derivative of arsenic, and its label did not bear a statement showing the substance from which such ingredient was derived.

Analysis of the alkaline compound powder showed that it consisted essentially of sodium hydroxide with small proportions of copper sulfate, sodium thiosulfate, sodium bicarbonate, and phenol, and a minute amount of phenolphthalein flavored with oil of anise. It was alleged to be adulterated in that it contained, for purposes of coloring only, a coal-tar color, namely, phenolphthalein, other than one from a batch that had been certified in accordance with regulations as provided by law. It was alleged to be misbranded in that the statements, "for the treatment of necrotic enteritis * * * Action: Systemic Alkalinizer. Use: To rebuild Alkaline Reserve of bodily tissues and fluids; as an aid in the treatment of Necrotic Enteritis (Swine) and Intestinal Infections of Poultry," borne on the label, were false and misleading since it would not be efficacious for such purposes.

Analysis of a sample of the Aresnol Compound Powder showed that it consisted essentially of arsenic trioxide (1.02 percent), powdered willow bark, linseed meal, and sulfur. It was alleged to be misbranded (1) in that the statements, (box label) "For the internal treatment of chronic supperative processes, such as Fistulour Withers, Poll Evil, Grease Heel, Catarrhal, Respiratory, Uterine Infections, etc., of the Horse," were false and misleading since it would not be efficacious for such purposes; and (2) in that it was fabricated from two or more ingredients and its label did not bear the common or usual name of each active ingredient, including the quantity or proportion of arsenic that it contained.

Analysis of the calcium gluconate compound solution showed that it contained approximately 15.05 percent of calcium gluconate and approximately 4 percent of boric acid. It was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and was represented to possess in that it was represented to contain 23 percent of calcium gluconate; whereas it contained not more than 15.05 percent of calcium gluconate. It was alleged to be misbranded (1) in that the statement (bottle label and carton) "Calcium Gluconate Comp. Solution * * * 23% Solution," was false and misleading; (2) in that the statement (bottle label) "Indications: * * * azoturia," was false and misleading since it would not be efficacious in the treatment of azoturia; and (3) in that its labeling was misleading since it failed to reveal the fact, material in the light of the representations therein, that it contained boric acid.

Analysis of the Diuretic Powder showed that it contained approximately 2.61 percent of methenamine, also sodium bicarbonate, potassium nitrate, and plant material including uva ursi, a resinous material, and an atropine-bearing drug such as belladonna. It was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and was represented to possess, since it was represented to contain 3 percent of methenamine; whereas it contained not more than 2.61 percent of methenamine. It was alleged to be misbranded (1) in that the statement, (carton label) "Contains Methenamine, 3%" was false and misleading; (2) in that the statement (carton) "Urinary disorders in horses, such as strangury, urinary retention associated with oedema

and febrile disturbances, acute intestinal inflammations," were false and misleading since it would not be efficacious for such purposes; and (3) in that it was fabricated from two or more ingredients and contained the alkaloids of atropine, hyoscine, and hyoscyamine, constituents of belladonna, but the label did not state the quantity or proportion of atropine, hyoscine, and hyoscyamine present, nor did it state the quantity or proportion of total alkaloids contained as constituents of belladonna.

Analysis of the Glucose Solution showed that it contained approximately 50 percent of anhydrous glucose. It was alleged to be misbranded in that the statements, "For the treatment of eclampsia, auto-intoxication. Also of value in Milk Fever * * * Adicosis * * * running fits and chronic diseases of a nervous nature," borne on the bottle label and carton, were false and misleading since it would not be efficacious for such purposes.

Analysis of the Potassium Arsenite Compound tablets showed that each tablet contained approximately 1.01 gram of arsenic as As_2O_3 per tablet, and that each tablet would make a solution containing not more than 0.854 gram of arsenic trioxide in 100 cc. It was alleged to be misbranded in that the statement, "Each tablet contains sufficient potassium arsenite to make four ounces of a solution whose arsenic content is the same as that of Fowler's Solution," borne on the bottle label, was false and misleading, since each tablet contained sufficient potassium arsenite to make a solution containing in each 100 cc. not more than 0.854 gram of arsenic trioxide; whereas Fowler's solution is a drug the name of which is recognized in the United States Pharmacopoeia, which provides that Fowler's solution, namely, solution of potassium arsenite, shall contain in each 100 cc. the equivalent of not less than 0.950 gram of As_2O_3, namely, arsenic trioxide.

Examination of the Canine Worm Tablets showed that the product consisted of capsules, each capsule containing a red-coated tablet and gray powder. Analysis showed that the tablets contained approximately 0.073 (1/14) grain of arecoline each and that the powder consisted essentially of sodium bicarbonate, a small proportion of santonin, and plant material including areca nut. The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and was represented to possess since each tablet was represented to contain 1/10 grain of arecoline, whereas each tablet contained not more than 0.073 (1/14) grain of arecoline. It was alleged to be misbranded in that the statement (on the bottle label) "Tablets * * * Contains: Arecoline * * * 1/10 gr.," was false and misleading. It was alleged to be misbranded further in that the statements (bottle label) "For Round * * * Worms in dogs and cats" and "Worm," were false and misleading since it would not be efficacious for such purposes.

Analysis of the Santonin-Calomel tablets showed that they contained santonin and calomel in approximately the quantities declared on the label, namely, "Calomel 1/8 Gr. Santonin 1/2 Gr." The article was alleged to be misbranded (1) in that the statement on the bottle label "Round worms in dogs and cats," was false and misleading since it would not be efficacious for such purposes; (2) in that it was fabricated from two or more ingredients and contained calomel, a derivative of mercury, but the label did not bear a statement showing that said ingredient was derived from mercury; and (3) in that the statement on the bottle label "Each c.c. contains a quarter grain each of strychnine Sulphate and Brucine Sulphate," was false and misleading.

The Tetrachlorethylene Capsules were alleged to be misbranded in that the statement on the bottle label, "For the removal of * * * round worms from all animals," was false and misleading since they would not be efficacious for such purposes.

Analysis of the Tonic Powder showed that it contained not more than 22 percent of phosphate and that it contained arsenic trioxide, sodium sulfate, iron sulfate, a calcium compound, and plant material including nux vomica, gentian, and quassia. It was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and was represented to possess, since it was represented to contain 28 percent of phosphate, whereas it contained not more than 22 percent of phosphate. It was alleged to be misbranded (1) in that the statements on the cartons, "1 Pound" and "Contains * * * Phosphate, 28%," were false and misleading since each of the cartons contained less than 1 pound of the powder and less than 28 percent of phosphate; (2) in that the statements on the cartons, "restorative. * * * improves digestion and assimilation of food," were false and misleading since it would not be efficacious for such purposes; (3) in that it was fabricated from two or more ingredients and contained strychnine; and (4) in that its container (bottle) was so filled as

to be misleading since the contents occupied not more than 30 percent of its total volume.

Analysis of the Guaiadine Tablets showed that they contained small proportions of potassium dichromate, iodine, guiacol, and creosote. The article was alleged to be misbranded in that the statements on the bottle label, "Indications: In the treatment of the so-called Fowl Cholera, Typhoid, Roup, Coccidosis and various troubles originating in the intestinal tract of fowls," were false and misleading since it would not be efficacious for such purposes.

Analysis of the Conjunctivitis #1 Tablets showed that they contained boric acid, zinc sulfate, salicylic acid, and methylene blue. They were alleged to be misbranded in that the statement "Conjunctivitis," borne on the bottle label, was false and misleading since they would not be efficacious in the treatment of conjunctivitis.

Analysis of the Liquid Nux Vomica Alkaloids showed that the article contained not more than 0.1503 (slightly less than 1/6) grain of strychnine sulfate and 0.0441 (1/23) grain of brucine sulfate, per cc. It was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and was represented to possess, since it was represented to contain 1/4 grain of strychnine sulfate and 1/4 grain of brucine sulfate per cc.; whereas it contained not more than 0.1503 (slightly less than 1/6) grain of strychnine sulfate and not more than 0.0441 (1/23) grain of brucine sulfate per cc. It was alleged to be constituent of the drug nux vomica, but its label failed to declare the quantity of strychnine that it contained.

On April 13, 1942, a plea of guilty was entered on behalf of the defendant and the court imposed a fine of $105 and costs.

776. Adulteration and misbranding of cod-liver oil. U. S. v. 5 Barrels and 1 Drum of Cod-Liver Oil. Default decrees of condemnation. Portion of product ordered disposed of for stock and poultry feed; remainder ordered destroyed. (F. D. C. Nos. 7567, 7586. Sample Nos. 71520-E, 80695-E.

This product differed from the pharmacopoeial standard since it was not partially destearinated, and it was off in color and odor and high in free fatty acids. The oil in the drum contained smaller amounts of vitamin D and vitamin A than those declared on the label.

On May 26 and 29, 1942, the United States attorneys for the Southern District of Ohio and Eastern District of Missouri filed libels against 5 30-gallon barrels of cod-liver oil at Mt. Orab, Ohio, and 1 30-gallon drum of cod-liver oil at St. Louis, Mo., which had been consigned on or about February 17 and April 4, 1942, alleging that the article had been shipped in interstate commerce by the Swiftide Co., from Portland, Maine; and charging that it was adulterated and misbranded. The article was labeled in part: "Swiftide Brand Cod Liver Oil."

It was alleged to be adultered in that it was represented as a drug the name of which is recognized in an official compendium but its quality fell below the standard set forth in that compendium and the manner in which it differed from such standard was not stated on the label.

It was alleged to be misbranded in that the name "Cod Liver Oil" was false and misleading since it was not cod-liver oil. A portion was alleged to be misbranded further in that the statements (drum) "Guaranteed to Contain Not Less Than 200 A. O. A. C. Units Vitamin D" and "Not less than 1,000 Units Vitamin A Per Gramme," were false and misleading since it contained not more than 100 A. O. A. C. units of vitamin D and not more than 700 U. S. P. units of vitamin A per gram. The oil in the drum was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in Notices of Judgment on Foods.

On June 30, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS[5]

DRUGS FOR HUMAN USE

777. Alleged misbranding of Armi Mineral Water. U. S. v. Ralph R. Markwood (Armi Mineral Water Co.). Demurrer to the information sustained. Case ordered dismissed. (F. D. C. No. 4114. Sample Nos. 5790-E, 27566-E.)

On June 24, 1941, the United States attorney for the Northern District of Ohio filed an information against Ralph R. Markwood, trading as the Armi

[5] See also Nos. 754, 757, 759, 765, 766, 772, 774.

Mineral Water Co. at Toledo, Ohio, alleging shipment on or about July 2 and August 15, 1940, from the State of Ohio into the State of Indiana of quantities of Armi Mineral Water which was misbranded.

Analysis of a sample of the article showed that it contained only traces of, if any, potassium diphosphate, manganese chloride, magnesium phosphate, potassium chloride, calcium phosphate, sodium phosphate, potassium iodide, ferric phosphate, or lithium bromide, and not more than 0.15 grain of silicon dioxide per quart (an insignificant quantity present in many city water supplies), and substantial amounts of sodium sulfate and lime.

It was alleged in the information that the article was misbranded: (1) In that the statements on the jug label, "Minerals Added Potassium Diphosphate Manganese Chloride Calcium Hydroxide Magnesium Phosphate Potassium Chloride Calcium Phosphate Sodium Phosphate Potassium Iodide Silicon Dioxide Sodium Sulphate Ferric Phosphate Lithium Bromide" were false and misleading since they represented that it contained important and substantial proportions of each one of the said substances; whereas it contained but inconsequential and unimportant proportions of, if any, potassium diphosphate, manganese chloride, magnesium phosphate, potassium chloride, calcium phosphate, sodium phosphate, potassium iodide, ferric phosphate, and lithium bromide. (2) In that its label did not bear the common or usual name of each active ingredient since one of its active ingredients was slaked lime, which was described on the label as calcium hydroxide, which is not its common or usual name. (3) In that the statement of the ingredients was not borne on the label in such terms as to render it likely to be understood by the ordinary individual under customary conditions of purchase and use since the ordinary individual would not understand that the various ingredients listed in the labeling, with the exception of lime and sodium sulfate, were present, if at all, in unimportant and inconsequential proportions. (4) In that the labeling was misleading since the zigzag design depicting lightning and the statement "Treated By Electrolysis," failed to reveal the fact which is material in the light of the representations made and suggested by the design and statement, that any treatment by electrolysis to which the article may have been subjected had not affected its properties. (5) In that the statement on the label, "Scientifically Balanced," was false and misleading when applied to water to which had been added small amounts of lime and sodium sulfate and inconsequential amounts of other substances.

On April 2, 1942, the defendant filed a general demurrer to the information; and on June 5, 1942, the court sustained the demurrer and ordered the case dismissed.

778. Misbranding of double strength solution of posterior pituitary. U. S. v. 2 Bottles of Double Strength Solution of Posterior Pituitary. Default decree of condemnation and destruction. (F. D. C. No. 7568. Sample No. 89434–E.)

This product was represented to possess a potency double that of posterior pituitary as defined in the U. S. Pharmacopoeia and therefore should produce per cubic centimeter an activity corresponding to not less than 160 percent of that produced by 0.005 gram of the standard powdered posterior pituitary; whereas samples taken from the two lots produced per cc. an activity corresponding in one instance to not more than 120 percent and in the other to not more than 100 percent of the activity produced by 0.005 gram of the standard powdered posterior pituitary. It also was represented to contain 20 International Units of posterior pituitary per cc., but samples were found to contain not more than 12 and 10 International Units, respectively, of posterior pituitary per cc.

On June 1, 1942, the United States attorney for the Southern District of New York filed a libel against 2 bottles containing a total of approximately 1½ liters of the above-named product at New York, N. Y., alleging that it had been shipped in interstate commerce on or about September 12, 1941, by Armour & Co. from Chicago, Ill.; and charging that it was misbranded in that the statements on the label, "Double Strength Solution of Post. Pituitary U. S. P. XI" and "20 I. U. per cc.," were false and misleading since its strength was not double that of solution of posterior pituitary as defined in the U. S. Pharmacopoeia, and it did not contain 20 International Units per cc.

On June 26, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

779. Misbranding of Arnold Garlic Tablets. U. S. v. 56 Packages and 60 Packages of Arnold Garlic Tablets. Default decree of condemnation and destruction. (F. D. C. No. 7352. Sample No. 87955–E.)

On April 16, 1942, the United States attorney for the Southern District of West Virginia filed a libel against the above-named product at Bluefield, W. Va., alleging that it had been shipped in interstate commerce on or about January 21, 1942, by Melrose Drug Co. from Cleveland, Ohio; and charging that it was misbranded.

Analysis showed that the article consisted essentially of starch and garlic.

The article was alleged to be misbranded in that the statement on the carton, "May be of Value in Reduction of Hyper-Tension," was false and misleading since it contained no ingredients which would be of value in the reduction of hypertension.

On June 16, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

780. Misbranding of Davis Formula No. 7895. U. S. v. 16 Packages and 10 Packages of Davis Formula No. 7895. Default decrees of condemnation and destruction. (F. D. C. Nos. 7341, 7962. Sample Nos. 23097–E, 95346–E.)

On April 21 and July 25, 1942, the United States attorney for the Northern District of California filed libels against 26 packages of Davis Formula No. 7895 at San Francisco, Calif., alleging that the article had been shipped in interstate commerce on or about December 17, 1941, and June 23, 1942, by E. R. Davis Prescription Co. from Bellingham, Wash.; and charging that it was misbranded.

Examination showed that each package of the article contained a small bottle of a solution of vitamin A and a larger bottle of the formula. Analysis of the formula showed that it consisted essentially of water, alcohol, potassium iodide, chloroform, sugar, and an extract of a plant drug such as lobelia.

The article was alleged to be misbranded in that representations in the labeling that it constituted an adequate treatment for asthma, hay fever, eczema, or rheumatic, neuritic or arthritic pains, were false and misleading since it would not be efficacious for such purposes.

On June 18 and December 24, 1942, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

781. Misbranding of Eff-Remin Dentifrice. U. S. v. 34 Packages and 11 Packages of Eff-Remin Dentifrice. Default decree of condemnation and destruction. (F. D. C. No. 7455. Sample No. 98285–E.)

On May 4, 1942, the United States attorney for the District of Massachusetts filed a libel against 34 packages, each containing 150 grams and 11 packages, each containing 300 grams of Eff-Remin Dentifrice at Boston, Mass., alleging that the article had been shipped in interstate commerce on or about April 22, 1942, by Goodrich & Love from New York, N. Y.; and charging that it was misbranded.

Analysis of a sample of the article showed that it consisted essentially of tartaric acid and salt and compounds of calcium, magnesium, and sodium including carbonates and sulfates, flavored with volatile oils and sweetened with saccharin.

The article was alleged to be misbranded in that the statements in the labeling (tin container) "Rub powder directly on gum margins or place some powder on thin layer of moist cotton wool and apply to affected areas," and (circular) "'Eff-Remin' Dentifrice is an effervescent remineralizing powder. It is of value in reducing sensitivity, for controlling decalcification due to erosion or dental caries, for 'soft' teeth * * * apply to affected areas," were false and misleading since they represented and suggested that when applied to affected areas, it would be of value in reducing sensitivity, in controlling decalcification due to erosion or dental caries, and for "soft" teeth; whereas when applied to affected areas it was of no value for such purposes.

It was also alleged to be misbranded in violation of the provisions of the law applicable to cosmetics, as reported in Notices of Judgment on Cosmetics.

On June 15, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

782. Misbranding of Pitcher's Castoria. U. S. v. 132 Bottles of Pitcher's Castoria. Default decree of condemnation and destruction. (F. D. C. No. 6525. Sample No. 75662–E.)

On December 18, 1941, the United States attorney for the District of Rhode Island filed a libel against 132 bottles of Pitcher's Castoria at Providence,

R. I., alleging that the article had been shipped in interstate commerce on or about November 10, 1941, by Roma Extract Co., Inc., from Boston, Mass.; and charging that it was misbranded.

Analysis of a sample of the article showed that it consisted essentially of extracts of plant drugs including senna, Rochelle salt (approximately 0.28 percent), sodium bicarbonate (2.5 percent), santonin (0.027 percent), flavoring materials (including methyl salicylate), sugar, and water. Examination showed that the carton containing the bottle was approximately 1½ inches taller than the bottle.

The article was alleged to be misbranded: (1) In that the statements on the retail carton and on the carton containing 1 dozen retail packages, "A Reliable Remedy for * * * Diarrhea due to Constipation, Worms, and Promotes Sleep by Overcoming these Disorders," were false and misleading since they created the impression that it was a reliable remedy for diarrhea due to constipation and worms, and would promote sleep by overcoming diarrhea due to constipation and worms; whereas it would not be efficacious for such purposes. (2) In that the names of its active ingredients did not appear on the label in such terms as to render them likely to be understood by the ordinary individual under customary conditions of purchase and use since the statement on the cartons. "Formula Alex. Senna, Pumpkin Seed, Anise Seed, Peppermint, Sod, Bicarbonate, Rochelle Salt, Worm Seed, Clarified Sugar, Wintergreen Flavor," did not reveal which of the substances mentioned were active ingredients. (3) In that its label failed to bear the common or usual name of each active ingredient since the label attached to the bottle did not contain the names of the active ingredients. (4) In that its container was so made and filled as to be misleading since the carton was materially larger than necessary to hold the bottle.

On April 22, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

783. Misbranding of Re-Duce-Oids Capsules. U. S. v. 53 Bottles of Re-Duce-Oids Capsules. Default decree of condemnation and destruction. (F. D. C. No. 5198. Sample No. 61308–E.)

On August 2, 1941, the United States attorney for the Eastern District of Washington filed a libel against 53 bottles of Re-Duce-Oids Capsules at Spokane, Wash., alleging that the article had been shipped in interstate commerce within the period from on or about April 7 to on or about June 9, 1941, by American Medicinal Products, Inc., from Los Angeles, Calif.; and charging that it was misbranded.

Analysis showed that the article was essentially a mixture of thyroid, potassium iodide, phenolphthalein, and milk sugar. Each capsule contained 0.92 grain of potassium iodide and 0.5 grain of thyroid.

The article was alleged to be misbranded in that the statements in the labeling which represented and suggested that it was an adequate and appropriate treatment for obesity were false and misleading, since it would not be efficacious for that purpose when used in accordance with the directions.

On September 11, 1941, the American Medicinal Products Co., claimant, having petitioned for a change of venue, an order was entered by the court transferring the action to the Northern District of California; and on September 18, 1941, the marshal was ordered to transmit the seized goods to that district. On July 13, 1942, the claimant having withdrawn its claim and answer, judgment of condemnation was entered and the product was ordered destroyed.

784. Misbranding of Special Formula 833. U. S. v. 130 Bottles of Special Formula 833. Consent decree of condemnation. Product ordered released under bond for relabeling. (F. D. C. No. 5956. Sample No. 51636–E.)

On October 4, 1941, the United States attorney for the District of Connecticut filed a libel against 130 bottles of Special Formula 833 at East Hampton, Conn., alleging that the article had been shipped in interstate commerce on or about June 13, 1941, by Brewer & Co., Inc., from Worcester, Mass.; and charging that it was misbranded.

Biological examination of a sample of the article showed that it contained approximately 1 milligram (333 International Units) of vitamin B_1 (thiamine chloride) per tablet.

It was alleged to be misbranded in that the following statements in the labeling were false and misleading since it would not constitute an adequate or effective treatment for the conditions mentioned nor would it be of especial value for

elderly men and women: "Vitamin B_1. Deficiency of this valuable vitamin may cause constipation, loss of vigor, various nervous and other important symptoms. This preparation is of especial value to elderly men and women."

It was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in Notices of Judgment on Foods.

On June 12, 1942, Brewer & Co., Inc., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond conditioned that it be relabeled under the supervision of the Federal Security Agency.

785. Misbranding of S-T-D "The" Hair Tonic. U. S. v. 4 Bottles, 21 Bottles, and 1 Bottle of S-T-D "The" Hair Tonic. Default decree of condemnation and destruction. (F. D. C. No. 7339. Sample No. 90314–E.)

On April 14, 1942, the United States attorney for the District of Massachusetts filed a libel against the above-named product at Springfield, Mass., alleging that it had been shipped in interstate commerce on or about December 17, 1941, by George A. Dustin from Chicago, Ill.; and charging that it was misbranded.

Analysis showed that the article consisted essentially of small proportions of potassium arsenite, sodium borate, and water. The potassium arsenite contained arsenic equal to 0.2 gram per 100 cc.

The article was alleged to be misbranded in that the following statements on the bottle labels were false and misleading: (Front) "Stops the Dandruff 'The' Hair Tonic for Dandruff Falling Hair Itching Scalp and all Scalp Ailments"; (back) "Wet Scalp with Ess-Tee-Dee Hair Tonic and massage every day until scalp is free from dandruff. * * * For best results, shampoo the hair once each week, then apply Ess-Tee-Dee Hair Tonic after hair has dried and continue applications every third or fourth day until scalp is free from dandruff and then use Tonic only as often as it is necessary to keep the scalp in a clean and healthy condition. * * * 'The' Hair Tonic."

It was also alleged to be misbranded under the provisions of the law applicable to cosmetics, as reported in C. N. J. No. 90.

On June 15, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

786. Misbranding of Vita Might Capsules. U. S. v. 9 Packages of Vita Might Capsules and 2 Cartons of Circulars. Default decree of condemnation and destruction. (F. D. C. No. 7509. Sample Nos. 80174–E, 80175–E.)

This product consisted of red capsules containing vitamins and black capsules containing minerals. The black capsules contained smaller amounts of minerals than those declared, and the labeling of both kinds of capsules bore false and misleading therapeutic claims.

On May 14, 1942, the United States attorney for the Northern District of Ohio filed a libel against 9 packages of Vita Might Capsules, and 2 cartons each containing approximately 1,500 circulars, at Cleveland, Ohio, alleging that they had been shipped in interstate commerce on or about February 28, 1942, by the Vital Foods Corporation from Chicago, Ill.; and charging that the article was misbranded.

Analysis of a sample of the black capsules showed that they contained dicalcium phosphate, peptonized iron, magnesium sulfate, manganese hypophosphite, copper peptonate, zinc sulfate, and potassium iodide. Vitamin assays of the red capsules showed that they contained 10,000 U. S. P. units of vitamin A, 1,000 U. S. P. units of vitamin B_1, and 1,000 U. S. P. units of vitamin D per capsule.

The article was alleged to be misbranded: (1) In that the black capsules failed to contain the represented amounts of iron, copper, zinc, magnesium, and manganese declared on the label, namely, "Iron ¾ Gr. Copper ⅛ Gr. Zinc $\frac{1}{25}$ Gr. Magnesium ⅔ Gr. Iodine $\frac{3}{2000}$ Gr. Manganese ⅔ Gr." (2) In that certain statements in the labeling were false and misleading since they represented and suggested that its use would result in longer life, good health, increased vigor, ambition and energy, improved sleep, lessening of fatigue, aches, pains and nervous strain; increased resistance to disease, colds and coughs; in beautiful teeth, skin, and hair; better digestion of food; healthy hair and skin; in growth, appetite, and muscular activity; freedom from skin disorders; good blood, fertility, and good teeth; that two out of three individuals are in need of vitamin supplements; and that the vitamin and mineral requirements of man cannot be obtained by consumption of ordinary foods; whereas its use would not accomplish such results, two out of three individuals are not in need of a vitamin supplement, and the vitamin and mineral needs of man can be obtained by consumption of

ordinary foods. (3) In that statements in the labeling regarding the efficacy of vitamins and minerals to promote healthy hair and skin; prevent night blindness; build resistance to colds, coughs, sinus; promote growth, healthy nerves, appetite, digestion, and muscular activity; minimize effects of alcohol; prevent certain skin disorders; heal lesions of lips at angles of mouth and of eyes and nose; promote growth and healing of wounds; prevent anemia, hemorrhage, pyorrhea, tuberculosis, and scurvy; form bones and teeth; prevent rickets; cure certain muscular and nerve diseases; restore color to gray hair; produce red corpuscles; produce hemoglobin; promote normal growth of body cells; influence muscle activity, digestion, and nerves; promote reproduction and growth; prevent goiter; aid heart, blood clotting, and brain cells; promote healthy bones and blood; and promote fertility, were misleading since alone or in connection with each other, they created the impression in the mind of the reader that it was an effective treatment for the symptoms and diseases mentioned and described; whereas it was not an effective treatment for such conditions.

The article was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in Notices of Judgment on Foods.

On June 22, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

787. Misbranding of Vita-Port Vitamin B_1 Tonic. U. S. v. 141 Bottles of Vita-Port Vitamin B_1 Tonic. Default decree of condemnation and destruction. (F. D. C. No. 7539. Sample No. 87177–E.)

On May 20, 1942, the United States attorney for the District of Columbia filed a libel against 141 bottles of Vita-Port Vitamin B_1 Tonic at Washington, D. C., alleging that the article was being offered for sale in the District of Columbia at the Super Cut Rate Drugs, Washington, D. C ; and charging that it was misbranded. The article was labeled in part: "Each fluid ounce contains thiamine hydrochloride (Vitamin B_1) . . . 4 mg. (Equivalent to 1330 International Units) Alcohol 20 Per cent."

It was alleged to be misbranded in that the following statements in the labeling, "Here's Health! * * * Recommended for Underweight—Loss of Appetite Nervousness," were false and misleading since it would not be an effective treatment for such conditions.

It was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in F. N. J. No. 3841.

On June 26, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

788. Misbranding of wheat embryo. U. S. v. 34 Cans of Wheat Embryo. Default decree of condemnation and destruction. (F. D. C. No. 6807. Sample No. 76077–E.)

On February 6, 1942, the United States attorney for the District of Minnesota filed a libel against 34 cans of wheat embryo at Minneapolis, Minn., alleging that the article had been shipped in interstate commerce on or about February 27, 1941, by Freshman Vitamin Co. from Detroit, Mich.; and charging that it was misbranded. It was labeled in part: "Dr. Ray Wheat Embryo."

It was alleged to be misbranded in that the statement on the label, "When indicated in Gastro-Intestinal Disorders, Dr. Ray Wheat Embryo should be cooked in with cereal for five minutes," was false and misleading in that it would imply that the article was of significant value in the treatment of all types of gastro-intestinal disturbances; whereas it was not.

The article was also charged to be misbranded under the provisions of the law applicable to drugs, as reported in F. N. J. No. 3842.

On June 15, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

789. Misbranding of Wise's Kollesol Tablets. U. S. v. 45 Bottles of Wise's Kollesol Tablets. Default decree of condemnation and destruction. (F. D. C. No. 7126. Sample No. 92501–E.)

On April 1, 1942, the United States attorney for the Southern District of California filed a libel against 45 bottles, each containing 300 tablets, of Wise's Kollesol at Los Angeles, Calif., alleging that the article had been shipped on or about January 22, 1942, by Wise's K. C. Homeopathic Pharmacy from Kansas City, Mo.; and charging that it was misbranded.

Analysis of a sample of the article showed that it consisted essentially of oxyquinoline sulfate, potassium sulfate, and lactose.

It was alleged to be misbranded in that representations in the labeling that it would eliminate bacteria, guard against toxins and ptomaines, promote healing, provide healthy granulation with a minimum of scar tissue, keep lesions from becoming infected, and control hemorrhage; that it would prevent diphtheria and other infections, both external and internal; that it would be useful in surgery, obstetrics, and gynecology as an all purpose antiseptic, would be useful for sterilizing instruments, for intrauterine use after removal of retained placental tissue, postpartum infection, or after curettage; that it was an adequate medication in dentistry for tootache, pyorrhea, trench mouth, gingivitis, bad teeth, and ulcerations of the buccal cavity; that it was an appropriate treatment for diseases of the eye, ear, nose, and throat including tonsillitis, septic sore throat and diphtheria; for conditions of the gastro-intestinal tract such as stomach ulcers, colitis, diarrhea, dysentery, typhoid fever, amoebic dysentery; conditions of the genito-urinary tract such as cystitis, balanitis, gonorrhea, chancroid, and syphilitic lesions; and for skin conditions including varicose ulcers; carbuncles, boils, burns, scalds, erysipelas, and athlete's foot, were false and misleading since it would not be efficacious for such purposes.

On April 22, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS FOR VETERINARY USE

790. Misbranding of Security Roup and Cold Remedy for Poultry, Security Worm Powder, and Security Gas Colic Remedy. U. S. v. The Jersee Co., Inc. (Security Food Co.) and Fred J. McCann. Pleas of guilty. Fine, $250. (F. D. C. No. 6425. Sample Nos. 43195–E, 43196–E, 49858–E, 57552–E.)

The labeling of these veterinary products bore false and misleading representations regarding their curative and therapeutic efficacy and also failed to comply with certain other labeling requirements of the law.

On May 18, 1942, the United States attorney for the District of Minnesota filed an information against the Jersee Co., Inc., doing business as the Security Food Co. at Minneapolis, Minn., and Fred J. McCann, president of Jersee Co., Inc., alleging shipment on or about February 22, March 17, and July 28, 1941, from the State of Minnesota into the States of Nebraska, Illinois, and Mississippi of quantities of the above-named drugs which were misbranded.

Analysis of a sample of Security Roup and Cold Remedy for Poultry showed that it consisted essentially of copper sulfate, potassium permanganate, and talc. It was alleged to be misbranded in that statements in the labeling which represented that when used in conjunction with certain specified procedures and certain sanitary measures, it would be efficacious in the treatment of roup and cold in fowl and poultry, that it would prevent fowl and poultry from contracting cold and roup, and that another drug, Security Cholera Remedy, would be efficacious in the treatment or prevention of bowel troubles in fowl and poultry, were false and misleading since the articles would not be efficacious for such purposes. It was alleged to be misbranded further in that the label failed to bear a statement of the quantity of the contents in terms of weight, measure, or numerical count and in that it was fabricated from two or more ingredients and the label failed to bear the common or usual name of each active ingredient.

Analysis of the Security Cholera Remedy showed that it consisted essentially of potassium alum, ferrous sulfate, and talc. It was alleged to be misbranded in that statements in the labeling which represented that it would be efficacious as a remedy for cholera in poultry; that it was a positive and quick relief for cholera, indigestion, dysentery, diarrhea, and all bowel troubles in poultry including chicks 1 or 2 months old and fowl over 2 months old; that it was a preventive against bowel irregularities in chicks and fowl; that when used in conjunction with certain specified procedures and certain sanitary measures it would be efficacious in the treatment of the said disease in fowl and poultry and that the use of another drug, Security Roup and Cold Remedy, would be efficacious in the treatment of roup and cold in fowl and poultry, were false and misleading since the articles would not be efficacious for such purposes. It was alleged to be misbranded further in that the labeling failed to bear a statement of the quantity of the contents in terms of weight, measure, or numerical count and in that it was fabricated from two or more ingredients and the label failed to bear the common or usual name of each active ingredient.

Analysis of the Security Worm Powder showed that it consisted essentially of sodium chloride, iron sulfate, sulfur, charcoal, and plant material including anise and areca nut. It was alleged to be misbranded in that statements in the labeling which represented that it was the safest and surest remedy in existence

for worms, that every lamb has worms in its stomach at birth, that worms may be easily prevented by judicious use of the article, that it was a standard remedy for worms in horses, sheep, swine, and cattle and was recommended by leading farmers and breeders to be a cheap and practical remedy for worms, that when administered to horses, it would regulate the bowels, blood, and digestive organs, that it would save feed by expelling worms, grubs, and bots, that the presence of worms in animals is usually due to a diseased condition of the system, that it would expel small worms from the large bowels and round or giant worms (*Eustrongylus gigas*) from the kidneys, bladder, and intestines, that it would tend to invigorate the digestive organs and bowels, that if administered to horses in the absence of worm symptoms it would prevent worms and would prevent horses getting in poor condition, that it was a mild purge, was harmless to the digestive organs and would leave the horses in better condition than before such administration, that it would prevent development of a new group of worms in horses, that it contained no poison or powerful drugs, that it would tend to correct the system so that worms would not be apt to return, would improve the general appearance of horses; whereas it was not the safest and surest remedy in existence for worms, every lamb does not have worms in its stomach at birth, it was not a standard remedy for worms in horses, sheep, swine, and cattle, and was not a cheap and practical remedy for worms, the presence of worms is not usually due to a diseased condition of the system, it was not harmless to the digestive system, would not leave horses in better condition than before such administration, it did contain poison or powerful drugs, it was not a mild purge, and would not be efficacious for the purposes for which it was recommended. It was alleged to be misbranded further (1) in that the label failed to bear an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; and (2) in that it was fabricated from two or more ingredients and the label failed to bear the common or usual name of each active ingredient.

Analysis of the Security Gas Colic Remedy showed that it consisted essentially of a hydroalcoholic solution containing volatile oils, ether, emodin-bearing plant material, sodium sulfite, and a trace of alkaloids. It was alleged to be misbranded in that statements in the labeling which represented that it was entirely different from all other colic remedies, that the moment it entered the stomach of the animal it neutralized the gases and acids in the stomach caused by the fermentation of food; that after administration, relief was immediate on the same principle as a chemical fire extinguisher; that when it reached the stomach it immediately formed other gases which subdued and neutralized those already there and which had caused colic; that one bottle was sufficient to cure colic in horses, mules, and cattle; that it would be efficacious in the cure, mitigation, treatment, and prevention of cases of kidney, wind or spasmodic colic, grippe, flatulent or acute indigestion; that it would be efficacious in the treatment of engorgement colic, obstruction colic, worm colic, flatulent colic, and spasmodic or cramp colic, and was a positive remedy for alfalfa or lucerne bloat; that it was a "security" remedy and was insurance against all forms of colic in horses, mules, and cattle, were false and misleading since it was not entirely different from other colic remedies and would not be efficacious for the purposes recommended. It was alleged to be misbranded further in that the label failed to bear an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count, and in that its label failed to bear a declaration of the common or usual name of each active ingredient.

On May 18, 1942, pleas of guilty having been entered on behalf of the defendants, the court imposed a fine of $250 as a general sentence on all counts for both defendants.

791. Misbranding of Security Gas Colic Remedy. U. S. v. 5 Cases and 1 Case of Security Gas Colic Remedy. Default decree of condemnation and destruction. (F. D. C. No. 6099. Sample No. 49858–E.)

The labeling of this veterinary product bore false and misleading therapeutic claims and also failed to contain a statement of the quantity of the contents and a list of the active ingredients.

On November 13, 1941, the United States attorney for the Southern District of Mississippi filed a libel against 6 cases containing a total of 26 bottles of Security Gas Colic Remedy at Bolton, Miss., alleging that the article had been shipped in interstate commerce on or about July 28, 1941, by the Security Food Co. from Minneapolis, Minn.; and charging that it was misbranded.

Analysis showed that the article consisted essentially of a hydroalcoholic solution containing volatile oils, ether, emodin-bearing plant material, sodium sulfite, and a trace of alkaloids.

The article was alleged to be misbranded in that statements in the labeling which represented that it was entirely different from all other colic remedies; that the moment it entered the stomach of the animal it neutralized the gases and acids in the stomach caused by the fermentation of food; that after administration, relief was immediate on the same principle as a chemical fire extinguisher; that when it reached the stomach it immediately formed other gases which subdued and neutralized those already there and which had caused colic; that one bottle was sufficient to cure colic in horses, mules, and cattle; that it would be efficacious in the cure, mitigation, treatment, and prevention of cases of kidney, wind or spasmodic colic, grippe, flatulent or acute indigestion; and that it would be efficacious in the treatment of engorgement colic, obstruction colic, worm colic, flatulent colic, and spasmodic or cramp colic, and was a positive remedy for alfalfa or lucerne bloat; that it was a "security" remedy and was an insurance against all forms of colic in horses, mules and cattle, were false and misleading since it was not entirely different from all other colic remedies and would not be efficacious for the purposes recommended.

It was alleged to be misbranded further in that the carton did not bear a statement of the quantity of the contents and in that the label did not bear a list of the active ingredients.

On May 5, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

792. Misbranding of Brown's Inhalant. U. S. v. 893 Cans and 37 Cans of Brown's Inhalant. Product ordered released to claimant. Amended order filed striking provision for release. Decree of condemnation. Product ordered released under bond for relabeling. (F. D. C. No. 7429. Sample Nos. 54740–E, 54741–E.)

On May 1, 1942, the United States attorney for the District of Delaware filed a libel against 893 gallon cans and 37 5-gallon cans of Brown's Inhalant at Dagsboro, Del., alleging that the article had been shipped in interstate commerce within the period from on or about January 31 to on or about April 9 and 17, 1942, by Brown's Poultry Products Co. from Lancaster, Pa.; and charging that it was misbranded.

Analysis showed that the article consisted essentially of kerosene and volatile oils including oil of citronella.

The article was alleged to be misbranded in that statements in the labeling regarding its efficacy in the treatment of diseases, symptoms, or conditions of the respiratory tract of poultry, such as colds, roup, brooder pneumonia, and other congestions of the respiratory tract, were false and misleading since it would not be efficacious for such purposes.

A. J. Timmons & Sons, Dagsboro, Del., appeared as claimant and denied the allegations of the libel and Edgar W. Brown, Lancaster, Pa., also petitioned for leave to intervene. On May 21, 1942, the court entered an order granting Edgar W. Brown leave to intervene and defend for himself and the other claimants, and also ordered the goods returned to A. J. Timons & Sons on condition that the labels which constituted the misbranding were removed or rendered illegible. On May 26, 1942, the Government moved to amend the order of May 21 by striking those portions which permitted a return of the seized property, which motion was granted after hearing, the court handing down the following opinion:

IN THE DISTRICT COURT OF THE UNITED STATES FOR THE DISTRICT OF DELAWARE

LEAHY, *District Judge*. "A libel was filed which sought seizure and condemnation of certain cans containing poultry medicine. The articles were shipped from Pennsylvania into Delaware. The libel charges misbranding of the product within the meaning of the Federal Food, Drug, and Cosmetic Act of June 25, 1938. The marshal made seizure. The claimants, who were in possession of the articles, filed an answer denying the property was misbranded. The manufacturer, Edgar W. Brown, an individual engaged in business under the name of 'Brown's Poultry Products Co.,' in Lancaster, Pa., was permitted to intervene on May 21, 1942, to defend the labeling on his own behalf. In the order permitting the intervention, there was a provision directing that the property be discharged from seizure and delivered to the claimant upon the claimant's filing bond; and that the claimant should not sell said property unless and until the labels were

removed. The reason offered to the court, in support of such procedure, was that it was admitted the contents of the cans were not deleterious and that merely the labels came within the prohibition of the statute. On May 26, 1942, the Government moved to amend the precipitous order of May 21, 1942, by striking out those portions which permitted a return of the seized property.

"In opposing the Government's motion, both the manufacturer and claimant assert that as this is a cause in admiralty, they should be allowed to have possession of the property before final hearing and decree by filing an appropriate bond in view of the fact that the statute provides that the procedure under section 334 (b) 'shall conform, as nearly as may be, to the procedure in admiralty.' Especially is this so in view of the fact that the Government admits, they argue, the contents of the cans are not harmful. The Government contends that there can be no release of seized property under the statute until 'after entry of the (final) decree' of condemnation.[6] A search discloses no decision dealing with the precise question raised.

"Sec. 334 (b) does state that the procedure 'in cases under this section shall conform, as nearly as may be, to the procedure in admiralty.' The argument of the claimants that the application of the admiralty rules should control the procedure as to release of seized products finds no support when we examine the admiralty rules. Rule 11 deals with release of perishable goods. Obviously this rule can hardly apply to non-perishable goods seized under sec. 334 (d). Rule 12 relates to the release of a vessel to the claimant upon the filing of bond to protect the claim of libelant.[7] Hence, it appears that there is no apposite admiralty rule or traditional practice upon the basis of which goods may be released prior to decree of condemnation.

"The legislative history of the present statute throws some light on the procedure intended by Congress. If we turn to sec. 10 of the Federal Food and Drugs Act of 1906,[8] it likewise appears that the release and delivery of the articles to the owners is only after the entry of a decree of condemnation.[9] The language of the various bills considered by Congress from 1933 to 1937 remained unchanged with respect to the release of articles and the giving of

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[6] 21 U. S. C. A. § 334 (d): "Any food, drug, device, or cosmetic condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may, in accordance with the provisions of this section, divert and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States; but such articles shall not be sold under such decree contrary to the provisions of this chapter or the laws of the jurisdiction in which sold: *Provided*, That after entry of the decree and upon the payment of the costs of such proceedings and the execution of a good and sufficient bond conditioned that such article shall not be sold or disposed of contrary to the provisions of this chapter or the laws of any State or Territory in which sold, the court may by order direct that such article be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this chapter under the supervision of an officer or employee duly designated by the Administrator and the expenses of such supervision shall be paid by the person obtaining release of the article under bond. Any article condemned by reason of its being an article which may not, under section 344 or 355, be introduced into interstate commerce, shall be disposed of by destruction."

[7] For an analogous situation, involving seizure of a vessel for forfeiture, see *The Pietro Campanella*, 41 F. Supp. 656, where the court said: "It is pointed out for the claimant that the statutes of the United States and the practice in admiralty do not permit the surrender of a libeled ship to the libelant except after formal decree of condemnation; and the analogous proceedings for forfeiture of other property are generally to the same effect."

[8] 21 U. S. C. A. § 14: "* * * seized for confiscation by a process of libel for condemnation. And if such article is condemned as being adulterated or misbranded, or of a poisonous or deleterious character, within the meaning of this act, the same shall be disposed of by destruction or sale, as the said court may direct, and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States, but such goods shall not be sold in any jurisdiction contrary to the provisions of this act or the laws of that jurisdiction: *Provided, however*, That upon the payment of the costs of such libel proceedings and the execution and delivery of a good and sufficient bond to the effect that such articles shall not be sold or otherwise disposed of contrary to the provisions of this act, or the laws of any State, territory, district, or insular possession, the court may by order direct that such articles be delivered to the owner thereof. The proceedings of such libel cases shall conform, as near as may be, to the proceedings in admiralty, except, that either party may demand trial by jury of any issue of fact joined in any such case, and all such proceedings shall be at the suit of and in the name of the United States."

[9] Three cases decided under the 1906 statute passed upon the release of goods to claimants. In *U. S. v. 9 Barrels of Butter*, 241 F. 499, the application for release was not made until after the entry of a decree of condemnation. In *A. O. Anderson & Co. v. United States*, 9th Cir. 284 F. 542, it would seem the court assumed the necessity of a prior decree of condemnation before release. In *U. S. v. 2 Cans of Oil of Sweet Birch, etc.*, 268 F. 866, it appeared that the claimant moved for release of the product before decree; but if I have failed to read the cases correctly and the motion was made, in fact, after decree, it would seem to make little difference as the court simply held that the motion was one addressed wholly to the court's discretion and the court declined to exercise it in favor of the claimant. Thus, no court, as far as I have been able to find, has held specifically that release may be had before decree, or that release may only be had after decree.

bond.[10] The various Senate Reports as well as the hearings had on the several proposed bills makes it manifest to me that Congress understood the procedure looked to the entry of a decree of condemnation before release of the seized articles.[11]

"Not only is the legislative history of sec. 304 helpful in determining its meaning, but a mere examination of the statute makes it clear that (1) an article may be proceeded against by libel when it is adulterated or misbranded; (2) once such an article is seized the issue of adulteration or misbranding must be determined by the court; (3) if the article is neither adulterated nor misbranded, it is released to the claimant; but (4) if it is adulterated or misbranded it may be disposed of only as provided by sec. 304 (d). Destruction or release may only be had after decree.

"I reject the contention of the claimants that the articles may be released prior to judicial determination of whether they were misbranded. Accordingly, the motion of the Government to amend the order of May 21, 1942, is granted. An order may be submitted striking out those portions of the May 21st order which permitted a return of the seized goods."

On June 15, 1942, judgment of condemnation was entered and the product was ordered released under bond conditioned that it be relabeled under the supervision of the Food and Drug Administration.

793. Misbranding of Emerson's Dead Shot. U. S. v. 18 Cans of Emerson's Dead Shot. Default decree of condemnation and destruction. (F. D. C. No. 6920. Sample No. 89121–E.)

On February 27, 1942, the United States attorney for the Southern District of New York filed a libel against 18 8-ounce cans of Emerson's Dead Shot at New York, N. Y., alleging that the article had been shipped on or about November 26, 1941, by the Emerson Products Co., Inc., from Newark, N. J.; and charging that it was misbranded.

Analysis of a sample of the article showed that it consisted essentially of calcium carbonate and fenugreek, with a small amount of a potassium compound, and not more than a trace of iron.

The article was alleged to be misbranded: (1) In that statements in the labeling which represented that it would be of value in the control, prevention, and removal of all species of worms infesting animals; in the control, prevention, and treatment of disease conditions of animals; and as a tonic and conditioner, were false and misleading since it would not be of value for such purposes. (2) In that it was a drug fabricated from two or more ingredients and the label failed to bear the common or usual name of each active ingredient.

On April 10, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

794. Misbranding of ADM Wheat Germ Oil. U. S. v. 141, 32, 21, and 17 Cans of Wheat Germ Oil With Accompanying Labeling. Consent decree of condemnation and destruction. (F. D. C. No. 5228. Sample Nos. 57684–E to 57687–E. incl.)

On July 28, 1941, the United States attorney for the Southern District of Iowa filed a libel against 141 quart cans, 32 4-ounce cans, and 38 pint cans of ADM Wheat Germ Oil with accompanying labeling at Des Moines, Iowa, alleging that the wheat germ oil had been shipped in interstate commerce within the period from on or about April 21 to on or about June 5, 1941, by Archer-Daniels-Midland Co. from Minneapolis, Minn.; and charging that it was misbranded.

Examination of samples of the article showed that it consisted of a bland oil possessing chemical and physical constants corresponding to those of wheat germ oil.

The article was alleged to be misbranded in that statements in the labeling which represented that it would be efficacious in the treatment and prevention of the various causes of breeding difficulties in cattle and other livestock, poultry, dogs, and foxes; that it would be efficacious in the treatment and prevention of sterility, impotency, failure to come on heat, missed breedings, false pregnancy, fetus resorption, abortion, premature birth, stillbirth, weak, puny

[10] S. 1944, 73d Cong., 1st and 2d Sess.; S. 2800, 73d Cong., 2d Sess.; S. 5, 74th Cong., 1st and 2d Sess.; S. 5, 75th Cong., 1st and 3d Sess.

[11] For the various Senate Reports and the hearings on the proposed bills, see Dunn, *Federal Food, Drug, and Cosmetic Act (1938)*, pp. 46, 61, 102, 206, 642, and 1,263 *et seq.*

calf, poor lactation, and diseases of the reproductive organs in cattle; and that it would be efficacious in the treatment and prevention of nonfertility, 4th day embryonic death, leukemia, poorly developed pullets, poor reproductive development, slow maturity, weak chicks, poor egg yield, poor hatchability, and various diseases in poultry; and that it would be efficacious in the treatment and prevention of sterility, impotency, partial fertilization, fetus resorption, abortion, stillbirth, weak, puny runts, poor lactation, mortality during nursing, diseases of reproductive organs, and small unprofitable litters in hogs, were false and misleading since it would be of no value for such purposes.

On June 16, 1942, the shipper and consignee, claimants, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered destroyed.

NONSTERILE SURGICAL DRESSINGS

795. Adulteration and misbranding of adhesive strips and first aid kits. U. S. v. 286¾ Gross Packages of Sani+Cross Adhesive Strips and 4⅝ Gross Tip Top Emergency First Aid Kits. Default decrees of condemnation and destruction. (F. D. C. Nos. 7364, 7617. Sample Nos. 83892–E, 89872–E.)

The Sani+Cross Adhesive Strips and the absorbent cotton, gauze, and compress in the first aid kits were contaminated with living micro-organisms. The first aid kits were misbranded since the boxes containing the absorbent cotton, adhesive tape, and compress were much larger than necessary; and no statement of the quantity of contents appeared on any of the labels.

On April 23 and June 9, 1942, the United States attorneys for the Southern District of New York and the Eastern District of Louisiana filed libels against 286¾ gross packages of adhesive strips at New York, N. Y., and 4⅝ gross first aid kits at New Orleans, La., alleging that the articles had been shipped in interstate commerce on or about January 27 and April 28, 1942, by Gero Products, Inc., from South Boston, Mass.; and charging that they were adulterated and misbranded.

The Sani+Cross Adhesive Strips were alleged to be adulterated in that their purity and quality fell below that which they purported and were represented to possess, i. e., they purported to be and were represented as being of such purity and quality that they were suitable for use on cuts and other wounds; whereas they were not suitable for such use since they were contaminated with living bacteria. They were alleged to be misbranded in that the following statements on the label, "Sani+Cross Adhesive Strips for Home, Factory, and Sport Use. Directions Wash wound with an antiseptic. Remove crinoline and apply gauze pad to the wound," were false and misleading since they represented and suggested that the article was a safe and appropriate bandage for first aid use on broken skin; whereas it was not safe and appropriate for such purposes.

The first aid kits were alleged to be adulterated in that they contained a package of an article which purported to be a drug recognized in the United States Pharmacopoeia, namely, absorbent cotton, but its quality or purity fell below the standard set forth in the pharmacopoeia since it was not sterile.

They were alleged to be misbranded (1) in that the statements, "First Aid Kit * * * For small cuts use 'Handi-Aid' or Adhesive Bandage * * * Be Prepared for Emergencies," were false and misleading when applied to kits containing items which were not sterile; (2) in that the labels failed to bear an accurate statement of the quantity of the contents; and (3) in that the containers were so made and filled as to be misleading.

On June 26 and July 3, 1942, no claimant having appeared, judgments of condemnation were entered and the products were ordered destroyed.

796. Adulteration and misbranding of Blue Cross First Aid Kits. U. S. v. 83¾ Dozen Blue Cross First Aid Kits. Consent decree of condemnation. Product ordered released under bond for reconditioning and relabeling. (F. D. C. No. 7067. Sample No. 59769–E.)

The absorbent cotton in these first aid kits was contaminated with viable micro-organisms; and the outside container of the kits failed to bear statements of the quantity of the contents and of the quantity or proportion of the mercury derivative (mercurochrome) contained in one of the items, i. e., the bottle of mercurochrome solution.

On March 19, 1942, the United States attorney for the District of Maryland filed a libel against the above-named product at Baltimore, Md., alleging that

it had been shipped in interstate commerce on or about February 16, 1942, from Philadelphia, Pa., by Sol Levy; and charging that it was adulterated and misbranded. The article was labeled in part: "Blue Cross First Aid Kit, Hampton Manufacturing Co., Carlstadt, New Jersey."

It was alleged in the libel that the cotton contained in the kits was adulterated in that it purported to be, and was represented as a drug the name of which is recognized in the Second Supplement to the Eleventh Revision of the United States Pharmacopoeia, which specifies among other things, that absorbent cotton must be sterile, but its quality or purity fell below the standard set forth in that compendium since it was not sterile but was contaminated with viable aerobic and anaerobic or facultative anaerobic micro-organisms.

The kits were alleged to be misbranded (1) in that the statement "First Aid Kit," borne on the cover of the kits, was false and misleading when applied to an article which was not sterile but was contaminated with viable micro-organisms; (2) in that the outside container did not bear an accurate statement of the quantity of the contents; and (3) in that the outside container did not bear a statement of the quantity or proportion of mercurochrome, a mercury derivative contained in the bottle of mercurochrome solution.

On June 17, 1942, the Hampton Manufacturing Co., Carlstadt, N. J., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond for reconditioning by removal and destruction of the nonsterile cotton and proper relabeling of the kits under the supervision of the Food and Drug Administration.

797. Adulteration and misbranding of Sani+Cross Adhesive Strips. U. S. v. 49½ Gross of Sani+Cross Adhesive Strips. Default decree of condemnation and destruction. (F. D. C. No. 7106. Sample No. 40897–E.)

On March 28, 1942, the United States attorney for the Eastern District of Pennsylvania filed a libel against 49½ gross of Sani+Cross Adhesive Strips at Philadelphia, Pa., alleging that the article had been shipped in interstate commerce on or about October 9, 1941, by the World Merchandise Exchange from New York, N. Y.; and charging that it was adulterated and misbranded.

It was alleged to be adulterated in that its purity and quality fell below that which it purported and was represented to possess, i. e., by its form and nature it purported and was represented to be of such purity and quality that it would be suitable for use on cuts and other wounds; whereas it was not suitable for such use since it was contaminated with living bacteria and the inconspicuous declaration on the package that the strips were not sterilized did not alter the character of an article represented as and purporting to be suitable for such use.

It was alleged to be misbranded in that the following statements appearing on the label "Sani+Cross Adhesive Strips for home, factory, and sport use. Directions. Wash wound with an antiseptic. Remove crinoline and apply gauze pad to the wound," were false and misleading since they represented and suggested that it was a safe, sanitary, and appropriate bandage for first aid use on broken skin; whereas it was not a safe and appropriate bandage for such use.

On May 1, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

798. Adulteration and misbranding of gauze bandages. U. S. v. 23 Dozen and 47 Dozen Packages of Gauze Bandages. Default decrees of condemnation and destruction. (F. D. C. Nos. 7419, 7793. Sample Nos. 66259–E, 80747–E.)

Examination of samples of this product showed that approximately one-half were contaminated with viable cocci or spore-forming micro-organisms.

On April 29 and June 29, 1942, the United States attorneys for the Southern District of Ohio and the Northern District of Illinois filed libels against 23 dozen packages of gauze bandages at Cincinnati, Ohio, and 47 dozen packages at Chicago, Ill., alleging that the article had been shipped in interstate commerce on or about February 16 and 18, 1942, from Carlstadt, N. J., by the Hampton Manufacturing Co.; and charging that it was adulterated and misbranded. The article was labeled in part: "Blue Cross 2 [or "1½"] inch 10 yds, Gauze Bandage Sterilized."

It was alleged to be adulterated in that its purity or quality fell below that which it purported or was represented to possess. It was alleged to be misbranded in that the statement "Sterilized" was false and misleading as applied to an article that was not sterile.

On June 11 and October 27, 1942, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

799. Adulteration and misbranding of gauze bandage. U. S. v. 179 Dozen Retail Packages of Gauze Bandage (and 3 other seizure actions against gauze bandage). Portion of product ordered released under bond to be resterilized; remainder ordered destroyed. (F. D. C. Nos. 7467, 7897, 8075, 8420. Sample Nos. 78914–E, 78915–E, 92536–E, 7250–F, 28507–F.)

All shipments of this product were contaminated with viable micro-organisms; and the cartons in one shipment were unnecessarily large.

On May 6, July 14, August 10, and September 24, 1942, the United States attorneys for the Southern District of California, Western District of Pennsylvania, Northern District of Georgia, and the District of Minnesota filed libels against the following quantities of gauze bandage—179 dozen packages at Los Angeles, Calif.; 48½ gross packages at Pittsburgh, Pa.; 153 dozen packages at Atlanta, Ga.; and 21 dozen packages at Minneapolis, Minn., alleging that the article had been shipped in interstate commerce on or about March 18, 20, and 25, May 1, and August 11, 1942, by Gotham Sales Co., Inc., from New York, N. Y.; and charging that it was adulterated and misbranded. It was labeled in part: "Gauze Bandage * * * Distributed by Gotham Sales Co. N. Y. C. [or "Distributors Chatham Sundries Co. New York NY"]."

The article was alleged to be adulterated in that its purity or quality fell below that which it purported or was represented to possess, namely, "Sterilized."

It was alleged in substance to be misbranded in that the statements (cartons in all shipments) "Sterilized after packaging," and (cartons of portions located at Los Angeles and Pittsburgh) "Designed to perfectly meet first aid requirements," were false and misleading as applied to an article that was contaminated with viable micro-organisms. A portion (seized at Minneapolis) was alleged to be misbranded further in that its container was so made, formed, and filled as to be misleading.

On May 26 and December 10, 1942, and January 22, 1943, no claimant having appeared for the seizures at Los Angeles, Minneapolis, and Atlanta, decrees were entered ordering that those at Los Angeles and Minneapolis be destroyed and that the portion of the product seized at Atlanta be sold after having been sterilized under the supervision of the Food and Drug Administration. On September 24, 1942, Gotham Sales Co., Inc., having admitted the allegations of the libel filed in Pennsylvania, judgment of condemnation was entered and the portion of the product seized at Pittsburgh was ordered released under bond conditioned that it be resterilized under the supervision of the Food and Drug Administration.

800. Adulteration and misbranding of sutures. U. S. v. 27 Cartons of Champion Dermal Sutures (and 3 other seizures of sutures). Decrees of condemnation. Portion of product ordered destroyed; remainder ordered released under bond to be sterilized. (F. D. C. Nos. 7583, 7584, 7788, 7814, 7833. Sample Nos. 31382–E, 76999–E, 77000–E, 77701–E to 77703–E, incl., 81664–E, 81665–E.)

On June 5, 1942, the United States attorney for the District of Colorado filed a libel against 27 cartons each containing 1 dozen sutures at Denver, Colo., which had been consigned by Gudebrod Bros. Silk Co. On June 22 and 26 and July 1, 1942, the United States attorneys for the District of Minnesota, Eastern District of New York, and Eastern District of Michigan filed libels against 12 packages each containing 1 dozen sutures at Minneapolis, Minn.; 36,532 envelopes of sutures at Brooklyn, N. Y.; and 23 dozen packages each containing 1 dozen sutures at Detroit, Mich., alleging that they had been shipped by Gudebrod Bros. Silk Co. The libels alleged that the article had been shipped in interstate commerce within the period from on or about June 18, 1941, to April 20, 1942, from Stowe, Pottstown, and Philadelphia, Pa.; and charged that it was adulterated and misbranded. It was labeled in part: "Champion Dermal Suture 000 [or "0000"] Fine 40 Inches"; or "Sizes 1–5–8 Two 18″ Strands of Each."

It was alleged to be adulterated in that its purity or quality fell below that which it purported or was represented to possess, namely, "Sterilized," since it was not sterile but was contaminated with living micro-organisms.

The portion of the article seized at Brooklyn, was alleged to be misbranded in that the statements, (envelopes) "Sterile * * * Caution—To prevent contamination, remove contents with disinfected hands or forceps only," were false and

misleading since they represented and suggested that it was sterile; whereas it was not. The remainder was alleged to be misbranded in that the word "Sterilized," borne on the envelopes, was false and misleading.

On June 19, 1942, the shipper having signed an acceptance of service and authorization for taking of final decree against the portion of the product seized at Denver, judgment of condemnation was entered and the product was ordered destroyed. On August 27, 1942, the shipper having admitted the allegations of the libel filed in the Eastern District of New York, the product was ordered released under bond conditioned that it be sterilized and repackaged under the supervision of the Food and Drug Administration. On September 3 and 8, 1942, no claimant having appeared for the seizures at Minneapolis and Detroit, judgments of condemnation were entered and the product was ordered destroyed.

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PRODUCTS

[1] Prosecution contested.
[2] Contains an opinion of the court.
[3] Permanent injunction issued.
[4] Violation of injunction.

SHIPPERS AND MANUFACTURERS

[2] Contains an opinion of the court.
[3] Permanent injunction issued.
[4] Violation of injunction.

D. D. N. J., F. D. C. 801–850 Issued December 1943

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

801–850

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States District Courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

WATSON B. MILLER,
Acting Administrator, Federal Security Agency.

WASHINGTON, D. C., *October 7, 1943.*

CONTENTS[1]

DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

801. Misbranding of Dr. Shreves' S-and-L Pills and Dr. Shreves' Anti-Gall-Stone Remedy. U. S. v. Ralph V. Toland (Dr. Shreves' Medicine Co.). Plea of guilty. Fine, $50 and costs. (F. & D. No. 4117. Sample Nos. 15549–E, 30909–E.)

On July 31, 1941, the United States attorney for the Southern District of Iowa filed an information against Ralph V. Toland, trading as Dr. Shreves' Medicine Co., Newton, Iowa, alleging shipment on or about June 19, 1940, from the State of Iowa into the State of Arkansas of a number of boxes of Dr. Shreves' S-and-L Pills which were misbranded, and on or about May 11, 1940, from the State of Iowa into the State of Indiana of a number of packages, each containing a bottle of Dr. Shreves' Anti-Gall-Stone Remedy, and an envelope containing a number of Dr. Shreves' S-and-L Pills which were also misbranded.

Analysis of a sample of the pills showed that they contained plant material, including a laxative plant drug, and metallic mercury with chalk, the two samples containing 0.62 grain and 0.68 grain respectively of mercury. Analysis of a sample of the gallstone remedy showed that it consisted essentially of lime water containing a white sediment and flavored with sassafras.

The pills were alleged to be misbranded in that they would be dangerous to health when used in the dosage or with the frequency or duration prescribed,

[1] For substitution of a drug and its sale under the name of another drug, see No. 820; omission of name and place of business of manufacturer, packer, or distributor, No. 845; omission of accurate statement of quantity of contents, Nos. 805, 809, 845; inconspicuousness of quantity of contents and active ingredients statements, Nos. 840, 849; omission of, or unsatisfactory, active ingredient statement, Nos. 809, 828, 839, 844, 845; deceptive packaging, No. 805.

recommended, or suggested in the labeling, (box and envelope) "Directions—One to three pills every night until the bowels move freely," and (circular enclosed in envelope) "Directions—Dose—One to three pills. For occasional Constipation, Biliousness and Sour Stomach, take two or three pills at bedtime, then follow with two pills every night until completely restored," since they contained mercury, a cumulative toxic substance. The pills which were shipped separately were alleged to be misbranded in that certain statements in the labeling, which represented that they would be efficacious as a treatment for biliousness and sour stomach, catarrh of the stomach or bowels, dizziness, nausea, diarrhea, or dysentery, would promote digestion and assimilation, and would restore tone to the system, were false and misleading since they would not be efficacious for such purposes. The combination Anti-Gall-Stone Remedy and Pills was alleged to be misbranded in that certain statements in the labeling which represented and suggested that it would be efficacious as a gallstone remedy, would produce a chemical change in the gall, would alter the secretions of the gall bladder, liver, kidneys, and bladder, would place the system in better condition and would maintain the stomach and intestines in a healthy condition, would overcome chronic constipation, would clean the alimentary canal, would prevent injury to the system by disease germs in the stomach and bowels, and would cleanse the system by removing poisons, would be efficacious in the treatment of billiousness, sour stomach, catarrh of the stomach or bowels, dizziness, nausea, diarrhea or dysentery, would promote digestion and assimilation and would restore tone to the system, were false and misleading since the combination would not be efficacious for such purposes.

On July 11, 1942, the defendant entered a plea of guilty and the court imposed a fine of $50 and costs.

802. Misbranding of UtraJel. U. S. v. 59 Boxes of UtraJel Regular and 8 Boxes of UtraJel Mild. Default decree of condemnation and destruction. (F. D. C. No. 7490. Sample Nos. 92548–E, 92549–E.)

On May 12, 1942, the United States attorney for the Southern District of California filed a libel against 58 boxes of UtraJel Regular and 8 boxes of UtraJel Mild, at Los Angeles, Calif., alleging that the articles had been shipped in interstate commerce on or about April 18, 1942, by the Pynosol Laboratories, Inc., from Chicago, Ill.

Analysis of a sample of the UtraJel Regular showed that it consisted essentially of soap, water, oil of pine, and combined iodine. Analysis of a sample of the UtraJel Mild showed that it consisted essentially of soap, water, and oil of pine.

The articles were alleged to be misbranded in that they would be dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, or suggested in the labeling since they might result in injury to the parts to which applied and to other organs of the body. The dosage recommendations were in part as follows: "As a Uterine Evacuant * * * Prepare field, gently insert sterilized applicator into the internal os and pass it carefully along the canal and into the mouth of the uterus remembering the position of the uterus as determined by previous bimanual examination. In all cases treatment should be administered very slowly to eliminate as much, the possibility of shock and excessive cramping. Dosage: 2 to 5cc first month, 8–10cc second month, 12–15cc third month and 20–22cc for farther advanced cases. Note: in some cases it may be necessary to increase dosage slightly, depending entirely on individual case * * * When no response is obtained after treatment, it is due either to uterine inertia or insufficient dosage. A great number of cases respond to a second treatment * * * The same procedure should be followed if portions of placenta are retained."

They were alleged to be misbranded further in that the following statements "Cervical Infections and Cervical Erosions (Minor) * * * Infections of the Cervical Canal (Minor) * * * Cystic Cervix," were false and misleading since the articles would not be effective treatments for the conditions mentioned, and in that the statements "UtraJel * * * As a Uterine Evacuant * * * UtraJel has been used successfully for induction of labor in full term deliveries, and for the expulsion of either entire or parts of placenta," were false and misleading since they represented and suggested that the articles were safe and appropriate for introduction into the uterine cavity, whereas they were not safe and appropriate for such use but were unsafe and dangerous and were capable of producing serious or even fatal consequences.

On August 10, 1942, no claimant having appeared judgment of condemnation was entered and the products were ordered destroyed.

803. Misbranding of castor oil. U. S. v. 29⅔ Dozen Bottles of Castor Oil. Default decree of condemnation and destruction. (F. D. C. No. 7575. Sample No. 89773–E.)

On May 29, 1942, the United States attorney for the Southern District of New York filed a libel against 29⅔ dozen bottles of castor oil at New York, N. Y., alleging that the article had been shipped in interstate commerce on or about April 21, 1942, by Ritchie & Janvier, Inc., from Bloomfield, N. J.; and charging that it was misbranded in that it would be dangerous to health when used in the dosage recommended in the labeling, namely, "Dosage: Infants Up to 1 year, 1 tablespoonful." The article was labeled in part: "Kellogg's Perfected Tasteless Castor Oil."

On July 22, 1942, the claimant having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered destroyed.

804. Misbranding of Dr. Hand's Worm Elixir. U. S. v. 23½ Dozen Bottles of Dr. Hand's Worm Elixir. Decree of condemnation and destruction. (F. D. C. No. 7137. Sample No. 31378–E.)

On April 1, 1942, the United States attorney for the Eastern District of Michigan filed a libel against 23½ dozen bottles of Dr. Hand's Worm Elixir at Detroit, Mich., alleging that the article had been shipped in interstate commerce by Smith, Kline & French Laboratories from Philadelphia, Pa., on or about February 17, 1942.

Analysis of a sample of the article showed that it consisted essentially of extracts of plant drugs, including santonin and a laxative drug, in a vehicle of syrup, a small proportion of alcohol, and flavoring material. Santonin was present in solution to the extent of 0.164 gram per 100 cubic centimeters and in the sediment to the extent of 0.065 gram per 100 cubic centimeters.

The article was alleged to be misbranded in that it was dangerous to health when used in the dosage and with the frequency or duration prescribed in the labeling, since the amount of santonin provided by the article when used in accordance with such directions was sufficient to produce serious poisoning. The dosage recommended was as follows: "DOSE—2 to 4 years, 1 teaspoonful; 4 to 6 years, 1½ to 2 teaspoonfuls; 6 to 10 years, 2 to 3 teaspoonfuls; adults, 4 teaspoonfuls. Give first dose at bedtime, second dose the first thing the following morning and third dose two hours later. Give a light diet while using the medicine. Do not repeat treatment for seven days. If the bowels have not moved freely within two hours after the third dose, give an enema or a quick acting cathartic, such as Epsom salt or citrate of magnesia until free movement has occurred. Do not give an oily cathartic."

On August 7, 1942, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS[2]

805. Adulteration and misbranding of Cherry Balsam and misbranding of Arabian Oil liniment, Mentho-Thymoline, Mettozone Tablets, Climax C. & P. R., and Bu-U Diuretic. U. S. v. Standard Drug Co., Inc. Plea of nolo contendere. Fine, $5.00. Fine suspended during good behavior. (F. D. C. No. 6446. Sample Nos. 37487–E to 37489–E, incl., 37796–E to 37799–E, incl.)

These products were misbranded because of false and misleading curative and therapeutic claims in the labeling and were further misbranded in the following respects: The labels of the Arabian Oil and the Mettozone Tablets, the former a rubefacient containing ammonia and turpentine and the latter containing zinc phosphide and cantharides, failed to bear necessary and adequate warning statements; the Cherry Balsam contained a smaller amount of chloroform than declared, the Mentho-Thymoline failed to bear a statement of the quantity of the contents and the cartons of the Cherry Balsam, Arabian Oil, Climax C. & P. R. and the Bu-U Diuretic were much larger than was necessary to hold the bottles.

On August 4, 1942, the United States attorney for the Western District of South Carolina filed an information against the Standard Drug Co., Inc., Spartanburg, S. C., alleging shipment on or about February 28 and March 13, 1941, from the State of South Carolina into the States of North Carolina and Georgia of quantities of the above-named drugs, all of which were misbranded; the Cherry Balsam was also adulterated.

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[2] See also Nos. 837, 845.

Analysis of a sample of the Cherry Balsam showed that it consisted essentially of extracts of plant drugs, chloroform 0.76 minim per fluid ounce, sugar, and water. It was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and was represented to possess, since it was represented to contain 2 minims of chloroform per fluid ounce, whereas it contained not more than 0.76 minim of chloroform per fluid ounce. It was alleged to be misbranded (1) in that its labeling bore false and misleading representations regarding its efficacy in the cure, mitigation, treatment or prevention of chronic coughs; (2) in that its container was so made, formed, and filled as to be misleading; and (3) in that the statements, "Chloroform 2 minims to Fl. Oz.," and "Each Fluid Ounce Contains 2 minims Chloroform," were false and misleading.

Analysis of a sample of the Arabian Oil showed that it consisted essentially of soap, ammonia, turpentine, and water. It was alleged to be misbranded (1) in that it was a rubefacient, containing ammonia and turpentine and might cause irritation of the skin, particularly if applied with rubbing, and it should not be allowed to get into the eyes or on the mucous membranes and its labeling did not bear warnings to that effect; (2) in that its labeling bore false and misleading representations regarding its efficacy in the cure, treatment or prevention of pain incident to rheumatism, lame back, stiff joints, croup, swellings, wounds, etc.; and (3) in that its container was so made, formed, and filled as to be misleading.

Analysis of a sample of the Mentho-Thymoline showed that it consisted essentially of small proportions of camphor, menthol, and thymol, incorporated in a petrolatum base. It was alleged to be misbranded (1) in that its labeling bore false and misleading representations regarding its efficacy in the cure or treatment of inflammations, colds, croup, sore throat, burns, wounds, piles, headache, and earache; (2) in that the name "Mentho-Thymoline" was misleading, since it suggested that the article consisted solely of menthol and thymol, whereas it did not so consist, but did contain other active ingredients; and (3) in that its label failed to bear an accurate statement of the quantity of the contents.

Analysis of a sample of the Mettozone Tablets showed that they consisted essentially of small proportions of extracts of plant drugs, including nux vomica, and a phosphide of some metal such as zinc. It was alleged to be misbranded: (1) In that it contained zinc phosphide, the frequent or continued use of which might lead to chronic phosphorus poisoning, and it contained cantharides, the use of which might cause nausea, vomiting, and abdominal pain and might seriously injure the kindeys, and its labeling did not warn of such dangers, and its use by persons afflicted by disease of the kidneys might be especially dangerous; (2) in that its labeling bore false and misleading representations regarding its efficacy in the cure, mitigation, treatment or prevention of sexual debility, weakened sexual powers, or impotency.

Analysis of a sample of the Climax C. & P. R. showed that it consisted essentially of extracts of plant drugs including capsicum, chloroform, alcohol, and water. It was alleged to be misbranded in that its labeling bore false and misleading representations regarding its efficacy in the cure, mitigation, treatment or prevention of pain in the bowels, cramp, colic, and diarrhea; and in that its container was so made, formed, and filled as to be misleading.

Analysis of a sample of the Bu-U Diuretic showed that it consisted essentially of extracts of plant drugs, small proportions of potassium acetate, alcohol, and water, preserved with sodium benzoate and colored with caramel. It was alleged to be misbranded in that representations in the labeling that it was a diuretic and would strengthen the kidneys and would assist in eliminating poisons and wastes from the system were false and misleading since it was not a diuretic, and would not be efficacious for the purposes claimed; and in that its container was so made, formed, and filled as to be misleading.

On September 14, 1942, the defendant having entered a plea of nolo contendere, the court imposed a fine of $5.00 and ordered that payment be suspended during good behavior by the defendant.

806. Adulteration and misbranding of W. K. Sterline's Compound. U. S. v. Webster K. Sterline (W. K. Sterline). Plea of guilty. Fine, $700; payment of $600 suspended. (F. D. C. No. 6417. Sample No. 5019-E.)

On March 7, 1942, the United States attorney for the Southern District of Ohio filed an information against Webster K. Sterline, trading as W. K. Sterline at Sidney, Ohio, alleging shipment on or about December 30, 1940, from the State

of Ohio into the State of Kentucky of a quantity of W. K. Sterline's Compound which was adulterated and misbranded.

Analysis of a sample of the article showed that it contained 15.25 grains of potassium iodide and 14.46 grains of sodium bromide per fluid ounce. (It contained 5.56 percent of alcohol by volume.)

The article was alleged to be adulterated in that its strength differed from that which it purported and was represented to possess in that the statements on the label, "Potassium Iodide 7.59 gr., Sodium Bromide 7.59 gr. * * * to each fluid ounce," represented and suggested that it contained not more than 7.59 grains of potassium iodide and not more than 7.59 grains of sodium bromide to each fluid ounce, whereas it contained 15.25 grains of potassium iodide and 14.46 grains of sodium bromide to each fluid ounce.

It was alleged to be misbranded (1) in that its label failed to bear adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health, or against unsafe dosage in such manner and form as are necessary for the protection of users since, because of the presence of potassium iodide, it should not be used in cases of lung disease, chronic cough, or goiter, and its use should be discontinued in the event a skin rash should appear; frequent or continued use might lead to mental derangement, skin eruptions, or other serious effects; and, because of the presence of sodium bromide, it should not be used by those suffering from kidney disease; (2) in that its labeling failed to bear adequate directions for use since the labeling failed to state that it should not be administered to children under 6 years of age; and (3) in that the statements, "Alcohol 10 Per Cent to each Fl. Oz.," and "Potassium Iodide 7.59 gr., Sodium Bromide 7.59 gr. * * * to each fluid ounce," were false and misleading since the article contained not more than 5.56 percent of alcohol, and contained 15.25 grains of potassium iodide and 14.46 grains of sodium bromide per fluid ounce.

On July 13, 1942, the defendant having entered a plea of guilty, the court imposed a fine of $350 on each of the 2 counts but suspended payment of $300 on each count, making the total fine paid $100.

807. Adulteration and misbranding of Howell's Cocoa & Quinine Syrup, Howell's Antiseptic Healing Oil, and Howell's Blue Label Cough Syrup, and misbranding of Howell's Epsom Salt, Hi-Qual Quinine Sulphate, and Howell's Hi-Qual Balm. U. S. v. The Howell Company, Inc. Plea of nolo contendere. Fine, $90. (F. D. C. No. 7264. Sample Nos. 9079–E, 9080–E, 35065–E, 35066–E, 35068–E, 35685–E.)

The labeling of the Healing Oil failed to bear adequate warning statements and bore false and misleading statements regarding its curative, therapeutic, and antiseptic properties The product also contained carbolic acid in excess of the amount claimed. The labeling of the Epsom salt failed to bear adequate directions for use and adequate warning statements. The Cocoa and Quinine Syrup was deficient in quinine sulfate. The Cough Syrup was deficient in chloroform. The bottles of quinine sulfate contained less than the labeled amount. The labeling of the Hi-Qual Balm bore false and misleading curative and therapeutic claims.

On July 9, 1942, the United States attorney for the Eastern District of Louisiana filed an information against the Howell Co., Inc., New Orleans, La., alleging shipment, within the period from on or about February 21, 1940, to on or about January 6, 1941, from the State of Louisiana into the States of Texas, Alabama, and Mississippi of quantities of the above-named drugs which were misbranded and portions of which were also adulterated.

Analysis of a sample of the Healing Oil showed that it consisted essentially of an oil containing camphor and 2.4 percent of phenol; tests showed that it was not antiseptic when used as directed. It was alleged to be adulterated (1) in that its strength differed from that which it purported and was represented to possess, since it was represented to contain 2 percent of carbolic acid, whereas it contained not less than 2.4 percent; and (2) in that its strength differed from and its quality fell below that which it purported to and was represented to possess, since it was represented to be an antiseptic but it was not an antiseptic.

The Healing Oil was alleged to be misbranded (1) in that its labeling failed to bear a warning that a bandage should not be used when the article was applied to fingers and toes, and that it should be applied according to directions and in no case to large areas of the body; (2) in that the statement, "2% Carbolic Acid," borne on the bottles and some of the cartons, and the statement, "Antiseptic," borne on the bottles and cartons, were false and misleading since the article contained more than 2 percent of carbolic acid, and it was not

an antiseptic; and (3) in that statements on the cartons containing a portion of the bottles that the article would be efficacious to relieve pain and soreness in carbuncles, erysipelas, boils, and itch, and would be efficacious in the treatment of ulcers, old sores, and skin eruptions, and statements on the cartons containing the remainder of the bottles that it would be efficacious in the treatment of piles and open sores, were false and misleading since the article would not be efficacious for such purposes.

The Epsom salt was alleged to be misbranded (1) in that its label failed to bear adequate directions for use since the label bore no directions for use; and (2) in that it was a cathartic and its label did not bear a warning that it should not be used when abdominal pain, nausea, vomiting or other symptoms of appendicitis are present, and that frequent or continued use might result in dependence on laxatives.

The Cocoa and Quinine Syrup was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and was represented to possess since it was represented to contain 2 grains of quinine sulfate per teaspoonful, but it contained not more than 1.65 grains of quinine sulfate per teaspoonful. It was alleged to be misbranded in that the statement, "Quinine Sulphate 2 Gr. per Teaspoonful," borne on the bottle label was false and misleading.

Analysis of a sample of the Cough Syrup showed that it consisted of a dark brown syrupy liquid containing 0.35 minim of chloroform per fluid ounce. It was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and was represented to possess, since it was represented to contain 3 minims of chloroform per fluid ounce, whereas it contained not more than 0.35 minimum of chloroform per fluid ounce. It was alleged to be misbranded in that the statement, "Chloroform 3 Min. per Fl. Oz." borne on the cartons and bottle labels was false and misleading.

The quinine sulfate was alleged to be misbranded in that the statement, "Quinine Sulphate 15 Grains," borne on the label of the bottle containing the article was false and misleading since the bottles contained quinine sulfate in amounts varying from 8.61 to 13.36 grains.

Analysis of a sample of the Hi-Qual Balm showed that it consisted of a mixture of oil of peppermint, oil of eucalyptus, camphor, menthol, and ephedrine in a petrolatum base. It was alleged to be misbranded in that the statements in the labeling which represented and suggested that it was efficacious in the treatment of head colds, croup, and piles were false and misleading since it was not efficacious for such purposes.

On July 22, 1942, a plea of nolo contendere having entered on behalf of the defendant, the court imposed a fine of $90.

808. Misbranding of Hillys "H-R 5." U. S. v. Morris William Hillinger (Hilly Medicinal Products). Plea of nolo contendere. Fine, $10. (F. D. C. No. 7268. Sample No. 55722–E.)

On June 11, 1942, the United States attorney for the Southern District of California filed an information against Morris William Hillinger, trading as Hilly Medicinal Products at Pasadena, Calif., alleging shipment on or about October 7, 1940, from the State of California into the State of Oregon of a quantity of Hillys "H-R 5" which was misbranded.

Analysis of a sample of the article showed that it consisted essentially of small proportions of an ephedrine salt, caffeine, sodium phosphate, reducing sugars, and water, and was colored with caramel.

The article was alleged to be misbranded (1) in that it contained 0.31 grain of ephedrine hydrochloride per fluid ounce but its label failed to warn that frequent or continued use might cause nervousness, restlessness, or sleeplessness, and that individuals suffering from high blood pressure, heart disease, diabetes, or thyroid trouble should not use such drug except on competent advice; and (2) in that certain statements in the labeling were false and misleading since they represented and suggested that the article would be efficacious for use after over-indulgence in alcohol; would be efficacious in the treatment of hang-overs; would help establish sobriety and would be efficacious in the cure, mitigation, treatment or prevention of alcoholism, whereas it would not be efficacious for such purposes.

On July 20, 1942, the defendant entered a plea of nolo contendere and the court imposed a fine of $10.

809. Misbranding of Bowel Regulator, Alterative Tonic Compound, and Neo-Sed. U. S. v. 72 Bottles of Bowel Regulator, 94 Bottles of Alterative Tonic Compound, and 93 Bottles of Neo-Sed. Default decrees of condemnation and destruction. (F. D. C. Nos. 7762, 7763, 7764. Sample Nos. 71935–E to 71937–E, incl.)

On June 15, 1942, the United States attorney for the Eastern District of Missouri filed libels against the above-listed drugs at St. Louis, Mo., alleging that they had been shipped in interstate commerce on or about January 7, 1942, by the Hale Drug Co., from Birmingham, Ala.

Analysis of a sample of the Bowel Regulator showed that it consisted essentially of compounds of sodium, potassium, magnesium and iron, tartrates, carbonates, extracts of plant drugs, including a laxative drug and an alkaloid-bearing drug, sugar, and water. It was alleged to be misbranded (1) in that its labeling failed to bear adequate directions for use since it was a laxative and the directions provided for no limitation as to the duration of use; (2) in that the labeling failed to bear adequate warnings that a laxative should not be taken in cases of nausea, vomiting, abdominal pain or other symptoms of appendicitis, and that frequent or continued use might result in dependence upon laxatives to move the bowels; (3) in that the statements in the labeling which represented and suggested that it would be an efficacious regulator of the bowels and stomach and would neutralize an acid condition of the body were false and misleading, since it would not be efficacious for such purposes; (4) in that it was fabricated from two or more ingredients and its label failed to bear a statement of the common or usual names of the active ingredients; and (5) in that it was in package form and its label failed to bear an accurate statement of the quantity of the contents.

Analysis of a sample of the Neo-Sed showed that it consisted essentially of barbital (0.7 grain per fluid ounce), compounds of sodium, ammonium and potassium, bromides, benzoic acid, sugar, and water. It was alleged to be misbranded (1) in that the labeling failed to bear adequate warnings that frequent or continued use may lead to mental derangement, skin eruptions or other serious effects, and that it should not be taken by those suffering from kidney diseases; (2) in that it was fabricated from 2 or more ingredients and the label failed to bear a statement of the common or usual names of the active ingredients, including a declaration of the quantity of bromide; and (3) in that it was in package form and its label failed to bear an accurate statement of the quantity of the contents.

Analysis of a sample of the Alterative Tonic Compound showed that it consisted essentially of methenamine, potassium iodide, a compound of iron, strychnine (0.01 grain per fluid ounce), extracts of plant drugs, including a laxative drug and an alkaloid-bearing drug, alcohol, sugar, and water. It was alleged to be misbranded (1) in that the statements in the labeling which represented and suggested that it would be efficacious as an alterative tonic and would be effective treatment for irritations caused by impurities of the blood, and would aid in the proper functioning of the bowels, kidney, and bladder were false and misleading, since it would not be efficacious for such purposes; and (2) in that it was fabricated from two or more ingredients and its label failed to bear a statement of the common or usual names of the active ingredients including the quantity of strychnine.

On September 2, 1942, no claimant having appeared, judgments of condemnation were entered and the products were ordered destroyed.

810. Misbranding of Bi-Lets. U. S. v. 4 Bottles and 5 Bottles of Bi-Lets. Default decree of condemnation and destruction. (F. D. C. No. 7622. Sample No. 94511–E.)

On June 9, 1942, the United States attorney for the Western District of Kentucky filed a libel against 4 bottles, each containing 500 capsules, and 5 bottles, each containing 100 capsules, of Bi-Lets, at Paducah, Ky., alleging that the article had been shipped in interstate commerce on or about March 10, 1942, by Bi-Lets, Inc., from Nashville, Tenn.

Analysis of a sample showed that the article consisted essentially of calomel, aloe, and bile. The article was alleged to be misbranded (1) in that it was a laxative and its labeling failed to warn that it should not be taken in cases of nausea, vomiting, abdominal pain, or other symptoms of appendicitis; and (2) in that its labeling failed to warn that frequent or continued use might result in dependence upon laxatives.

On September 15, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

811. Misbranding of Brown's Nosopen. U. S. v. 12 Cartons of Brown's Nosopen. Default decree of condemnation and destruction. (F. D. C. No. 7640. Sample No. 83803–E.)

On June 16, 1942, the United States attorney for the Southern District of Texas filed a libel against 12 cartons of Brown's Nosopen at Houston, Tex., alleging that the article had been shipped in interstate commerce on or about January 7, 1942, from Lawton, Okla., by the Am-Bro Co.

Examination showed that the article contained 2 units designated "No. 1 Solution" and "No. 2 Solution," respectively. Analyses of samples showed that the No. 1 solution consisted essentially of ephedrine sulfate (approximately 1 percent), chlorobutanol, and water; and that the No. 2 solution consisted essentially of ephedrine alkaloid (approximately ¾ percent), and small proportions of volatile oils including camphor, menthol, and oil of eucalyptus in a mineral oil base.

The article was alleged to be misbranded (1) in that both solutions contained ephedrine but the labeling failed to warn that frequent or continued use might cause nervousness, restlessness, and sleeplessness and that it should not be used by individuals suffering from high blood pressure, heart disease, diabetes, or thyroid trouble except upon competent advice, and in that the No. 2 solution contained mineral oil and its labeling failed to warn frequent or excessive use might cause injury to the lungs and that it should not be given to infants and younger children except on competent advice; (2) in that its name, "Nosopen," was false and misleading since it represented and suggested that it would open the nasal passages and make breathing easier, whereas it would not accomplish such results; and (3) in that a statement on the label, "Discomforts of Hay-Fever, Asthma, Sinus-Head-Colds," was false and misleading since it represented and suggested that the article would be efficacious for all discomforts of the conditions described, whereas it would be effective only to lessen nasal congestion.

On July 31, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

812. Misbranding of Texas Crystals. U. S. v. 47 Packages of Texas Crystals. Default decree of condemnation and destruction. (F. D. C. No. 7585. Sample No. 78303–E.)

In addition to failure to bear such warnings as are necessary for the protection of users, the labeling of this product failed to declare that sodium sulfate was the only ingredient present in an appreciable amount.

On May 29, 1942, the United States attorney for the District of Maryland filed a libel against 47 packages of Texas Crystals at Baltimore, Md., alleging that the article had been shipped in interstate commerce on or about April 8 and May 1, 1942, by Loye Distributing Co. from Fairmont, W. Va.

Analysis of a sample of the article showed that it consisted of hydrated sodium sulfate with traces of other inorganic salts.

The article was alleged to be misbranded (1) in that it was a laxative and its labeling failed to warn that a laxative should not be taken in cases of nausea, vomiting, abdominal pain, or other symptoms of appendicitis, and that frequent or continued use might result in dependence upon laxatives; (2) in that the statement appearing on the label, "Analysis sodium sulphate, calcium carbonate, sodium chloride, magnesium carbonate, potassium chloride, sodium carbonate, traces of iron and aluminum oxide," was misleading since it failed to reveal the fact that the article did not contain appreciable amounts of any ingredient except sodium sulfate.

On July 21, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

813. Misbranding of Purola Female Pills. U. S. v. 44 Packages of Purola Female Pills. Default decree of condemnation and destruction. (F. D. C. No. 6864. Sample No. 93031–E.)

On February 18, 1942, the United States attorney for the Western District of Washington filed a libel against 44 packages of Purola Female Pills at Seattle, Wash., alleging that the article had been shipped in interstate commerce on or about November 19, 1941, by McKesson & Robbins, Inc., from Portland, Oreg. The article was labeled in part: "Purola Female Pills * * * Packed for Blumauer-Frank Drug Co. Portland, Oregon."

Analysis showed that the article consisted essentially of laxative plant drugs including aloes, oil of tansy, alkaloidal material, probably derived from ergot, and iron sulfate.

It was alleged to be misbranded (1) in that it was a laxative when used as directed, but its labeling failed to bear warnings that it should not be used

when abdominal pain, nausea, vomiting, or other symptoms of appendicitis are present, and that frequent or continued use might result in dependence upon laxative; (2) in that the statements (carton) "Female Pills" and (slip in box) "Take one pill three times daily for four or five days previous to expected period," were false and misleading since they created the impression that it would be effective in promoting the menstrual flow, whereas it would not be so effective.

On July 22, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

814. Misbranding of Stevens Concentrated Mineral Water. U. S. v. 67 Bottles of Stevens Concentrated Mineral Water. Default decree of condemnation and destruction. (F. D. C. No. 7522. Sample 87789–E.)

On May 15, 1942, the United States attorney for the District of Columbia filed a libel against the above-named product at Washington, D. C., alleging that the article had been shipped in interstate commerce on or about March 2, 1942, by E. A. Stevens, from Dawson Springs, Ky.

Analysis of a sample of the article showed that it consisted essentially of water, magnesium sulfate, calcium sulfate and small proportions of sodium sulfate, sodium chloride, calcium carbonate, and potassium chloride.

The article was alleged to be misbranded (1) in that its labeling failed to bear adequate directions for use since it was a laxative and the directions provided for continuous administration, whereas a laxative should not be used continuously; (2) in that its labeling failed to warn that a laxative should not be taken in cases of nausea, vomiting, abdominal pain, or other symptoms of appendicitis, and failed to warn that its frequent or continued use might result in dependence upon a laxative; and (3) in that statements in the labeling which represented and suggested that it had given remarkable results for years in many of the ailments of the human system, was efficacious as a regulator and would be efficacious to maintain and restore health, would be efficacious in the treatment of liver, kidney, and stomach trouble, dropsical trouble, rheumatism, malaria, and poor appetite, loss of weight, nervousness, headaches, gas on the stomach, sleeplessness, pains in the legs and a generally depressed condition of the spirits, stomach trouble, constipation, pains in the side, gall-bladder trouble, dead liver, chronic gastric, prostrated gland suffering, flu, run-down condition, acute and chronic nephritis, bedema, dyspnoea and anasarca with indications for the elimination of both fluids and toxins to prevent uremia, engorged condition of the liver or kidneys, gout or any of the uric acid diatheses, bilious conditions, jaundice, intestinal derangements, anemias chlorasis, all blood and constitutional diseases, sluggish portal circulation, coated tongue, and sallow complexion, were false and misleading since the article would not be efficacious for such purposes.

On June 29, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS[3]

815. Adulteration and misbranding of milk of magnesia. U. S. v. Certified Pharmacal Co., Inc. Plea of guilty. Fine, $40. (F. D. C. No. 6461. Sample No. 53412–E.)

On June 30, 1942, the United States attorney for the Southern District of New York filed an information against the Certified Pharmacal Co., Inc., New York, N. Y., alleging shipment on or about December 9, 1940, and June 19, 1941, from the State of New York into the State of California, of quantities of milk of magnesia which was adulterated and misbranded.

The article was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, and its strength differed from and its quality fell below the standard set forth therein, since samples taken from each of the two shipments showed the presence of 5.85 percent and 5.93 percent of magnesium hydroxide respectively, and its difference in strength and quality from the standard was not plainly stated on its label. The United States Pharmacopoeia provides that milk of magnesia shall contain not less than 7 percent of magnesium hydroxide.

It was alleged to be misbranded in that the label statements "Milk of Magnesia

[3] See also Nos. 805, 806, 807.

U. S. P.," and "Contains not less than 7% * * * of Magnesium Hydroxide," were false and misleading since the article did not comply with the specifications of the United States Pharmacopoeia.

On August 24, 1942, a plea of guilty having been entered on behalf of the defendant, the court imposed a fine of $40.

816. Adulteration of ampuls of strontium bromide, triple distilled water, iron and arsenic, sodium iodide, Lactosan, and Solution Sal-Ar-Sodide. U. S. v. Cornelius L. Johnson (Haarlem Research Laboratories). Plea of guilty. Total fine, $325. (F. D. C. No. 5557. Sample Nos. 24371–E, 24373–E to 24376–E, incl., 24385–E, 24391–E, 28036–E, 34842–E.)

On August 5, 1942, the United States attorney for the Southern District of New York filed an information against Cornelius L. Johnson, trading as the Haarlem Research Laboratories at New York, N. Y., alleging shipment within the period from on or about the month of February, to on or about October 7, 1940, from the State of New York into the States of Pennsylvania, Maryland, and New Jersey of quantities of ampuls of the above-named drugs which were adulterated.

The strontium bromide was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and was represented to possess since it purported and was represented to contain 15½ grains of strontium bromide in each 10 cc., whereas it contained not more than 12.59 grains of strontium bromide per 10 cc.

The triple distilled water was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the National Formulary, and its quality or purity fell below the standard set forth in such compendium since its contained sulfates and chlorides, ingredients which are not found in the official product and contained oxidizable substances in excess of the amounts permitted by the Formulary and the residue from 100 cc. was greater than the maximum permitted, 0.002 gram, and its difference from such standard was not plainly stated on its label.

The 2 shipments of iron and arsenic were alleged to be adulterated in that their strength differed from that which they purported and were represented to possess since the article in one shipment purported and was represented to contain in each 5 cc., 7.75 milligrams of iron and 32 milligrams of arsenic, whereas it contained in 5 cc. not less than 10.7 milligrams of iron and not less than 97.9 milligrams of arsenic; and the article in the other shipment was represented to contain in each 10 cc., 15.5 milligrams of iron and 64 milligrams of arsenic, whereas it contained in each 10 cc., not less than 24 milligrams of iron and not less than 190 milligrams of arsenic.

The sodium idodide was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the National Formulary, and its quality and purity fell below the standard set forth therein since it was not a clear aqueous solution but contained flocculent precipitate and its difference from such standard was not plainly stated on its label.

The Lactosan was alleged to be adulterated in that its strength differed from, and its quality fell below that which it purported and was represented to possess, as it was represented to contain in each 2 cc., ¾ grain of casein and 9/10 grain of sodium phosphate, whereas it contained in each 2 cc., not more than 0.304 (3/10) grain of casein, and not more than 0.370 (less than 2/5) grain of sodium phosphate.

The Solution Sal-Ar-Sodide was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and represented to possess since it purported and represented to contain in each 20 cc., 31 grains of sodium salicylate and 31 grains of sodium iodide, whereas it contained in each 20 cc., not more than 26.2 grains of sodium salicylate and not more than 27.4 grains of sodium iodide.

On September 10, 1942, the defendant having entered a plea of guilty, the court imposed a fine of $100 on each of the second and third counts of the information, which involved the ampuls of triple distilled water and the 5 cc. ampuls of iron and arsenic, and imposed a fine of $25 on each of the remaining five counts, a total of $325.

817. Adulteration and misbranding of digitalis leaves capsules. U. S. v. Philadelphia Capsule Co., Inc., and Joseph McManus. Pleas of nolo contendere. Defendants found guilty. Fines, $250. (F. D. C. No. 7285. Sample No. 54329–E.)

On August 19, 1942, the United States attorney for the Eastern District of Pennsylvania filed an information against the Philadelphia Capsule Co., Inc.,

Philadelphia, Pa., and Joseph McManus, alleging shipment on or about September 9, 1941, from the State of Pennsylvania into the State of New Jersey of a quantity of digitalis leaves capsules.

The article was alleged to be adulterated in that its strength differed from that which it purported and was represented to possess since it was represented to contain 1 grain of digitalis leaves per capsule but it contained not more than 0.4 grain. It was alleged to be misbranded in that the label statement, "Capsules Digitalis Leaves Approximates 1 Gr.," was false and misleading.

On September 16, 1942, the defendants having entered please of nolo contendere, the court found them guilty and imposed a fine of $125 against each defendant.

818. Adulteration and misbranding of Estrovin. U. S. v. 950 ampuls of Estrovin. Default decree of condemnation and destruction. (F. D. C. No. 7634. Sample Nos. 7697–E, 7698–E.)

The potency of this product was not greater than 1,100 international units of estrogenic ovarian follicular hormones per cubic centimeter, whereas it was represented to possess a potency of 5,000 such units per cubic centimeter.

On June 10, 1942, the United States attorney for the Southern District of California filed a libel against 950 ampuls of Estrovin at Los Angeles, Calif., alleging that the article had been shipped in interstate commerce on or about January 28, 1942, by the Adson-Intrasol Laboratories, Inc., from New York, N. Y.

The article was alleged to be adulterated in that its strength differed from that which it was represented to possess, namely, 5,000 international units of estrogenic ovarian follicular hormones in each cubic centimeter.

It was alleged to be misbranded in that the following statements in the labeling: (Box containing 25 ampuls) "Estrovin in Oil * * * 1 c. c. contains therapeutic activity of 5,000 i.u. of estrogenic ovarian follicular hormones," (individual ampul) "Estroin in Oil 1 c. c. 5,000 I.U." were false and misleading, since 1 cubic centimeter of the article did not contain the therapeutic activity of 5,000 international units of estrogenic ovarian follicular hormones.

On August 7, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

819. Adulteration of wheat germ. U. S. v. 161 Cases and 45 Cases of Wheat Germ. Default decree of condemnation and destruction. (F. D. C. No. 8399. Sample No. 16874–F.)

On September 24, 1942, the United States attorney for the Southern District of New York filed a libel against 161 cases, each containing 12 ½-pound cans, and 45 cases, each containing 12 1-pound cans, of wheat germ at New York, N. Y., alleging that the article had been shipped in interstate commerce on or about August 28, 1942, by the Battle Creek Food Co. from Battle Creek, Mich. The article was labeled in part: "Battle Creek Wheat Germ."

Examination of samples of the article showed that it contained less than 300 U. S. P. units of vitamin B_1 per ounce.

The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it was represented on its label as possessing, 500 U. S. P. units of vitamin B_1 per ounce.

It was alleged to be misbranded (1) in that the statements on the label, "One ounce (approx. ⅓ cup) of Battle Creek Wheat Germ supplies 500 U. S. P. units of vitamin B_1 (Thiamin), (1½ times the minimum daily requirement for an adult)," was false and misleading since it contained less than 500 U. S. P. units of vitamin B_1 per ounce; and (2) in that the statements, "Wheat Germ fills a much-needed place in the modern diet which is apt to be deficient in Thiamin (vitamin B_1) and Riboflavin (vitamin G). Vitamin B_1 tends to make steady nerves, improves appetite, aids digestion and combats constipation. Vitamin G promotes good nutrition; both vitamins help to build vital resistance. Battle Creek Wheat Germ presents a * * * economical source of these important vitamins. One ounce (approx. ⅓ cup) of Battle Creek Wheat Germ supplies 500 U. S. P. units of vitamin B_1 (Thiamin), (1½ times the minimum daily requirement for an adult)," were misleading since they represented and suggested that adequate amounts of vitamin B_1 and riboflavin are not supplied by the ordinary diet and that the use of the article would promote steady nerves, improve the appetite, aid digestion, combat constipation, promote good nutrition, and build vital resistance, whereas vitamin B_1 and riboflavin are present in a wide variety of ordinary foods and are present in many ordinary diets in adequate amounts, and the use of the article would not correct or promote the conditions mentioned.

The article was also charged to be misbranded under the provisions of the law applicable to foods as reported in F. N. J. No. 4488.

On October 10, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

820. Adulteration and misbranding of nicotinic acid amide. U. S. v. 57 Bottles and 314 Bottles of Nicotinic Acid Amide. Default decrees of condemnation. Product ordered relabeled and delivered to State hospitals. (F. D. C. No. 8069, 8099. Sample Nos. 28408–F, 29121–F, 29131–F.)

On August 10 and 12, 1942, the United States attorneys for the Northern and Southern District of Georgia filed libels against 57 bottles and 314 bottles of nicotinic acid amide at Atlanta and Savannah, Ga., alleging that the article had been shipped in interstate commerce on or about July 1 and 24, 1942, by Schieffelin & Co. from New York, N. Y. The article was labeled in part: "Nicotinic Acid Amide."

The article was alleged to be adulterated in that nicotinic acid had been substituted in whole or in part for nicotinic acid amide.

It was alleged to be misbranded in that the declaration on the label "Nicotinic Acid Amide" was false and misleading, and in that it was offered for sale under the name of another drug.

On September 15 and December 21, 1942, no claimant having appeared, judgments of condemnation were entered and the courts ordered that the article be delivered to the Florida State Hospital and to a State hospital at Midgeville, Ga., after it had been relabeled under the supervision of the Food and Drug Administration.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS[4]

DRUGS FOR HUMAN USE

821. Action to restrain interstate shipments of Catalyn and other drugs. U. S. v. Royal Lee (Vitamin Products Co.). Permanent injunction granted. (Inj. No. 12.)

On June 19, 1941, the United States attorney for the Eastern District of Wisconsin filed a complaint against Royal Lee, trading as Vitamin Products Co., Elm Grove, Wis., alleging: (1) That the defendant was engaged in the manufacture, processing, and packing of vitamin and mineral products at Milwaukee, Wis., for introduction and delivery for introduction, distribution, and sale in interstate commerce under the firm name Vitamin Products Co. (2) That in connection with such business the defendant had designated, appointed, directed, and managed agents and distributors located in various cities in the United States and Canada and was continuing to do so. (3) That the following products, Catalyn, also known as V-P No. 710 Vitamin Tablets; V-P Vitamin A Complex, also known as V-P No. 711 Vitamin Tablets; V-P Vitamin B complex, also known as V-P No. 712 Vitamin Tablets; V-P Vitamin C Complex, also known as V-P No. 713 Vitamin Tablets; V-P Vitamin D Complex, also known as V-P No. 714 Vitamin Tablets; V-P Vitamin F Complex, also known as V-P No. 716 Vitamin Tablets; V-P Vitamin G Complex, also known as V-P No. 717 Tablets; V-P Phosphate, also known as V-P No. 718 Liquid; Cerol, also known as V-P No. 719 Vitamin Tablets; V-P Organic Mineral Tablets, also known as V-P No. 721 Mineral Tablets; and Cerodyn, had been manufactured, processed, and packed by the defendant at Milwaukee, Wis., and had been and were being introduced and delivered for introduction into interstate commerce by the defendant at Milwaukee, Wis., to his agents and distributors for sale, were being sold to the public, and remained in interstate commerce under the direction and control of the defendant.

The complaint alleged further that the product "Catalyn," also known as V-P No. 710 Vitamin Tablets, was fabricated from more than two active ingredients, namely, wheat flour, wheat bran, crystalline milk sugar, powdered rice bran, powdered carrots, and glandular material; that the product V-P Vitamin A Complex, also known as V-P No. 711 Vitamin Tablets, was fabricated from more than two active ingredients, namely, wheat starch and tissues, rice bran, root tissues resembling those of dried carrot, milk sugar, and animal tissues suggestive of glandular material; that the product V-P Vitamin B Complex, also known as V-P No. 712 Vitamin Tablets, was fabricated from more than two active ingredients, namely, wheat tissues and starch, rice bran, animal tissues apparently from

[4] See also Nos. 801, 805–809, 811–820.

a glandular source, milk sugar, root tissues resembling those from carrot, and apparently a yeast by-product; that the product V-P Vitamin C Complex, also known as V-P No. 713 Vitamin Tablets, was fabricated from more than two active ingredients, namely, wheat starch and tissues, milk sugar, rice bran, animal tissues closely resembling glandular material, and material of the nature of small droplets of a light green color suggesting chlorophyl origin; that the product V-P Vitamin D Complex, also known as V-P No. 714 Vitamin Tablets, was fabricated from more than two active ingredients, namely, crystalline calcium lactate, crystalline milk sugar, and material closely resembling calcium glycerophosphate; that the product V-P Vitamin F Complex, also known as V-P No. 716 Vitamin Tablets, was fabricated from more than two active ingredients, namely, wheat bran, starchy material, rice bran, animal tissues from glandular source, and occasional alfalfa hairs; that the product V-P Vitamin G Complex, also known as V-P No. 717 Vitamin Tablets, was fabricated from more than two active ingredients, namely, crystalline milk sugar, wheat starch and wheat tissues, and animal tissues apparently from a glandular source; and charged that the said products were misbranded in that their labels failed to bear the common or usual name of their active ingredients.

The complant alleged further (1) that prior to February 8, 1939, the defendant manufactured, processed, and packed, and introduced and delivered for introduction into interstate commerce, the product known as Catalyn; (2) that labels and circulars packed with the product, prior to that date, bore false and misleading claims and representations as to its therapeutic value in the treatment of human ailments and diseases; (3) that on February 8, 1939, in the District Court for the Western District of Wisconsin, the defendant was convicted of violation of the Food and Drugs Act of 1906 in that he had introduced into interstate commerce a quantity of Catalyn which was misbranded by reason of false and fraudulent therapeutic claims for it; and (4) that since February 8, 1939, the defendant had removed from the labels of his product Catalyn all claims and representations therefor of therapeutic value in the treatment of human ailments and diseases, and since that date none of the other above-mentioned products had contained, either on the labels of the products or packages or in circulars enclosed therewith, any direct statement or representation of therapeutic value for the products in the treatment of human ailments and diseases.

The complaint alleged further (paragraph 15) that since February 8, 1939, the defendant had written and caused to be written and printed at Milwaukee, Wis., various circulars, pamphlets, booklets, and other literature relative to the articles, wherein and whereby the defendant had and was representing that they were efficacious in the cure, prevention, and treatment of a wide variety of human diseases and ailments.

Paragraphs 16 to 22 of the complaint charged that the defendant by means of the said circulars, pamphlets, booklets, and other literature had, and was representing (1) that the products when taken individually or collectively as prescribed, recommended, or suggested in the labeling would cure, prevent, and constitute an adequate treatment for human diseases such as pneumonia, tuberculosis, influenza, colds, whooping cough, measles, and mumps, which representations were false and misleading since such diseases are caused by infection with germs or viruses and not by a deficiency of vitamins or minerals, and no vitamin or mineral, or any combination thereof, or any product or combination of products manufacturerd by the defendant was capable of curing, preventing, or constituting an adequate treatment for any of such diseases: (2) that representations that such products would cure, prevent and constitute an adequate treatment for puerperal sepsis, infection of ear, infections of genito-urinary tract, infections of mucous tract, infections of gastro-intestinal tract, infection of respiratory tract, infections of sinuses, focal infections, and infectious diseases, were false and misleading since no mineral or vitamin or combination thereof nor any product or combination of products above-mentioned manufactured by the defendant, was capable of curing, preventing, or constituting an adequate treatment for any such diseases; (3) that representations that they would cure, prevent, or constitute an adequate treatment for high blood pressure, low blood pressure, overweight, and underweight, were false and misleading since no substance or combination of substances would correct or constitute a cure, preventive, or adequate treatment for both high blood pressure and low blood pressure, overweight and underweight; (4) that representations that they would cure, prevent, and constitute an adequate treatment for arteriosclerosis, high blood pressure, aortic aneurism, aortic insufficiency, valve leakage,

coronary occlusion, coronary thrombosis, or dementia, were false and misleading since such diseases are almost always accompanied by irreparable anatomical changes that are incurable and for which no substance or combination of substances, including minerals, and/or vitamins, or a product or any combination of products manufactured by the defendant would constitute an adequate treatment, preventive, or cure; (5) that representations that they would cure, prevent, and constitute an adequate treatment for arthritis, hemorrhagic conditions of the urine, albuminuria, heart disorders, menstrual and ovarian disorders, Bright's disease, leg ulcers, anemia, wasting of muscles, paralysis, muscular weakness, chronic diseases, amenorrhea, colitis, cystitis, children's diseases, women's diseases, liver disorders, dysmenorrhea, eczema, gall-bladder disease, gastritis, eye disorders, and cardiovascular disturbances, were false and misleading since such diseases have a multiplicity of causes and no mineral or vitamin or combination thereof, or any product of combination of the products of the defendant, would constitute an adequate or competent treatment for such diseases and conditions; (6) that representations that the drugs would cure, prevent, and constitute an adequate treatment for acne, acute or chronic alcoholism, angina pectoris, Addison's disease, adrenal hypertrophy, agranulocytosis, apoplectic sequellae, atrophy of glands or muscles, achlorhydric anemias, backward children, burns, cataracts, chlorosis, chorea, diabetes mellitus, epilepsy, toxic goiter, hyperthyroidism, hyperglycemia, hypertension, hypotension, asthma, hay fever, hyperemesis of pregnancy, sexual impotency, insanity due to endocrine failure, menopause disorders, migraine, menstrual dysfunction, paralysis agitans, phlebitis, poliomyelitis, paralytic sequellae, pancreatic dysfunction, pernicious anemia, nephritis, ideopathic ovarian disorders, prostate enlargement, peptic ulcers, sclerosis, rheumatic fever and varicose veins, were false and misleading since such diseases are not recognized by experts qualified by scientific training and experience as being caused by a deficiency of either minerals and/or vitamins, and no vitamin or mineral or any combination thereof, or any product or combination of products of the defendant would constitute an adequate or competent treatment, prevention, or cure for any of said diseases; (7) that representations that they would cure, prevent, and constitute an adequate treatment for atrophy of organs and glands (testes, liver, spleen, thyroid, pituitary and salivary), infections and degenerations of eyes, physical weakness, nervousness, insomnia, gland swelling in general, renal calculi, bronchitis, endocrinopathies of childhood, nervous indigestion, neurasthenia, disorders of pregnancy, sterility, hypogalactia, retarded growth, loss of hair, fatty infiltration and degeneration of the liver, symptoms of nerve degeneration, Paget's disease, paresthesias, defective teeth, thyroid dysfunction, diarrhea, vomiting, dermatosis, gastro-enteritis, infantile gastro-intestinal disorders, glycosuria, malnutrition, sprue, low resistance, kidney and bladder disorders, renal dysfunction, formation of stones (calculi), excessive growth of lymphoid tissue, lymphatic gland enlargement, loss of weight and vigor, low vitality, stunted growth, emaciation, enlargement of liver, kidney and spleen, acidosis, and would prevent carcinoma, were false and misleading since such symptoms and conditions are indicative of a wide variety of fundamentally different diseases, which require divergent forms of treatment such as surgery, psychotherapy, endocrine, drug vaccine and physical therapy, and no mineral or vitamin or combination thereof, or any product or combination of products manufactured by the defendant, would constitute an adequate or competent treatment, prevention, or cure for such diseases and conditions

The complaint alleged further (paragraphs 23 and 24) that supplies of the circulars, pamphlets, booklets, and other literature containing false and misleading representations as hereinbefore set forth, were maintained by the defendant at Milwaukee, Wis., and that since February 8, 1939, he had, on his own volition and in response to requests therefor, shipped in interstate commerce to his agents and distributors quantities of said literature which were shipped apart from his products; that he had on occasion shipped quantities of literature in the same shipments as said products; that the agents and distributors had on hand concurrently, quantities of such literature and products and by virtue of the power and control exercised by the defendant over his agents and distributors, he had and was requiring and causing such agents and distributors, to place such literature with his products while being held for sale by the agents and distributors after shipment in interstate commerce, and that thereby the defendant had so acted so as to cause the misbranding of the products in violation of the law.

The complaint alleged further that the defendant would continue to ship the product in interstate commerce and would continue to cause the circulars, pamphlets, booklets, and other literature containing the false and misleading representations to accompany the product unless enjoined; that it was distinctly in the public interests that an injunction should issue for the reason, among others, that many of the diseases for which the products were recommended, suggested, or prescribed in the labeling, such as diabetes, Addison's disease, coronary thrombosis, pernicious anemia, agranulocytosis, pneumonia, and tuberculosis, are serious conditions requiring prompt, adequate treatment; that reliance on the use of the products of the defendant, in the treatment of said diseases would preclude prompt, appropriate, and adequate treatment of the person suffering therefrom with resulting irreparable injury and even death; that because of inability to sample, examine, and seize each interstate shipment of these products, many shipments of the misbranded products would enter into interstate commerce and the practice of the defendant in misbranding the products while they were held by his agents and distributors after shipment in interstate commerce could not be eliminated effectively except through the process of injunction, and that the purpose of the law would thus be frustrated and endangered unless an injunction issue; and prayed that the court grant a preliminary injunction to be effective until the conclusion of the trial of the case, and that on final hearing the preliminary injunction be made permanent.

On July 17, 1941, the defendant filed an answer alleging that all the persons and firms listed in the complaint as agents and distributors, with the exception of (1) Vitamin Products Co., Boston, Mass.; (2) Catalyn California Co., M. R. Pexton and A. L. Jason, Los Angeles, Calif.: (3) Catalyn California Co., and J. W. Egan, San Francisco, Calif.; (4) W. A. Pansky, Mandan, N. Dak., and; (5) Mrs. W. F. Madden, Orlando, Fla., were jobbers buying the products from the defendant and reselling them for their own account and profit; that these designated "1," "2," and "3," were factory branches of the defendant and that those designated "4," and "5," were agents of said "jobbers." The defendant in his answer admitted the shipment of the drugs and the literature substantially as alleged in the complaint, except that he denied that the drugs and the literature were ever shipped together. The answer also denied that the business and affairs of the jobbers were directed by the defendant, that the jobbers were agents of the defendant, that the literature described was labeling, and that the defendant had so acted as to cause the misbranding of his products as alleged.

On April 12, 1941, as the result of a pre-trial conference, it was stipulated that the question of whether the facts set forth in paragraphs 15 to 24, inclusive, of the complaint stated a cause of action, be submitted to the court.

On September 11, 1941, the issues having been submitted to the court on written briefs and arguments of counsel, the following opinion was handed down:

F. RYAN DUFFY, *District Judge.*

"This is a civil action wherein the plaintiff seeks an injunction against the defendant under the provisions of the Federal Food, Drug, and Cosmetic Act (Sec. 332, U. S. C., Title 21), for alleged violation of Sec. 331 (a), (b), and (k), Title 21, U. S. C., for shipment of misbranded articles of drugs, as defined by Sec. 352 (a) and (e), Title 21, U. S. C.

"At the pre-trial conference herein, the parties entered into a stipulation, for the purpose of clarifying the issues, that prior to the trial of this action, the court should determine whether plaintiff's complaint, paragraphs 15 to 24 inclusive, states a claim upon which relief can be granted against the defendant; that is to say, whether the acts alleged in said paragraphs constitute such acts with reference to a food or drug, while held for sale after shipment in interstate commerce, as are prohibited in Sec. 331 (k), Title 21, U. S. C.

"The paragraphs in question allege that the defendant has caused to be written and printed various circulars, pamphlets, booklets, and other literature making therapeutic claims for the products which are manufactured by the defendant. In particular, the Government claims that said literature falsely represents that the products will cure and constitute adequate treatment for a long list of human ailments. It is alleged that such literature is sent in interstate commerce to agents and distributors of said products, separately from the products to which they relate. It is further alleged that the defendant, by virtue of his power and control over said agents and distributors, requires that they place the separately shipped literature so as to be displayed with the products of the defendant while

held for sale. The question to be determined is whether the act of bringing written, printed, or graphic matter containing false and misleading therapeutic claims, in the presence of, proximity of, and in association with an article, after shipment in interstate commerce, is a misbranding of that article within the meaning of the term 'misbranding' as that term is defined in the act.

"Sec. 331, Title 21, U. S. C. A. provides:

> The following acts and the causing thereof are hereby prohibited: * * * (k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to a food, drug, device, or cosmetic, if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded.

"Sec. 352 (a) provides that a drug is deemed misbranded if its labeling is false or misleading in any particular. Sec. 321 (m) defines labeling:

> The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

"The allegations of the complaint concerning the falsity and misleading character of defendant's literature are, for the purpose of deciding this question, deemed to be true.

"Plaintiff admits that the alleged misbranding is not a physical tampering with the labeling, or a tampering with the product itself. Plaintiff contends that the misbranding occurs through the device of causing written, printed, and graphic matter, containing false and misleading therapeutic claims, to be shipped through interstate commerce separately from the product; and that at the destination, such written, printed, and graphic matter becomes associated with and used in proximity and in the presence of the transported product on the shelves, display counters, and in the window displays on the premises of defendant's agents and distributors.

"In determining the intent of Congress, it may be helpful to recall some of the legislative history of the act in question, which at that time was commonly called the 'Copeland Bill.' The bill, as introduced, gave jurisdiction to enforce same to the Department of Agriculture. It was generally known at that time that the Federal Trade Commission desired to enforce any provisions as to false advertising. While the Copeland Bill was pending, Public Act. No. 477 was passed (approved March 21, 1938), which measure specifically gave jurisdiction over false advertising of foods, drugs, and cosmetics to the Federal Trade Commission. Thereafter the Copeland Bill was amended and, as passed (approved June 25, 1938), gave jurisdiction to the Department of Agriculture to enforce the provisions as to adulteration, packaging, and labeling; but the enforcement as to false advertising remained in the Federal Trade Commission. On June 30, 1940, the enforcement of the Federal Food, Drug, and Cosmetic Act was transferred from the Department of Agriculture to the Federal Security Agency.

"As this action is brought under the Federal Food, Drug, and Cosmetic Act, we are not here concerned with any false advertising by the defendant. We must determine whether there was a misbranding by false or misleading labeling.

"The plaintiff necessarily contends for an extremely broad interpretation of the language of the act defining labeling:

> (m) The term 'labeling' means all labels and other written, printed, or graphic matter * * * (2) accompanying such article.

The Government contends that when Congress said 'accompanying such article', it did not necessarily mean accompanying in the ordinary sense of the word, as long as the literature eventually came together with the products before or when offered for sale.

"Congress did intend that labeling should be something more than the printed or written matter actually affixed to the article itself. It undoubtedly had in mind the practice of manufacturers of placing circulars and printed matter in cartons, which literature would not be affixed to the product to be sold.

"However, it would be a case of legislation by judicial construction to say that literature 'placed on shelves, display counters, or in window displays' (to use the language of the Government) comes within the definition of labeling. It is advertising, pure and simple. The Congress could have provided that all written or printed matter displayed near or in proximity of the article was labeling but it did not do so. Suppose defendant provided a sign, extolling the virtues of his product, to be hung on the wall? Under the construction contended by the Government, it could be considered labeling. What about a

billboard across the street? At what point could a line be drawn where labeling would end and advertising begin?

"In view of the fact that Congress decided that evils in the field of advertising as to food, drugs, and cosmetics were to be handled by the Federal Trade Commission, and the Copeland Bill was therefore amended accordingly, there is no justification for any court to put a strained and unnatural construction upon the term 'labeling.' Furthermore, the Food and Drug Act is a criminal statute. In *U. S. v. Weitzel*, 246 U. S. 533, the Supreme Court stated (p. 543):

* * * Statutes creating and defining crimes are not to be extended by intendment because the court thinks the legislature should have made them more comprehensive * * *.

To the same effect, see *Walter W. Oeflein, Inc., v. The State*, 177 Wis. 394, 396.

"It is my opinion that paragraphs 15 to 24 inclusive of the complaint do not state a claim against the defendant upon which relief can be granted."

On November 24, 1941, on motion of the United States attorney the complaint was amended in order to strike the charge that the labels did not bear the common or usual name of each active ingredient of the products. On December 5, 1941, on motion of the defendant, the court ordered the complaint dismissed. On December 15, 1941, the Government filed a notice of appeal to the Circuit Court of Appeals for the Seventh Circuit from the order dismissing the complaint. On November 25, 1942, the Circuit Court of Appeals overruled the District Court's decision, handing down the following opinion:

Before EVANS and KERNER, Circuit Judges, and LINDLEY, District Judge.

KERNER, *Circuit Judge*. "This is an appeal from a decree dismissing plaintiff's complaint for an injunction against violations of § 301 (a), (b), and (k) for the shipment of misbranded articles of drug and § 502 of the Federal Food, Drug, and Cosmetic Act of 1938, c. 675, 52 Stat. 1040; 21 U. S. C. A., § 331 (a), (b), and (k) and § 352 (a).

"The complaint charged that defendant had caused to be printed circulars making therapeutic claims for the products which he manufactures, falsely claiming that the products will cure and constitute adequate treatment for human ailments; that such circulars were sent in interstate commerce to agents and distributors of said products, separately from the products to which they relate; and that by virtue of defendant's power and control over his agents and distributors, he required them to display the separately shipped circulars with defendant's products.

"We must decide whether the act of bringing printed matter containing false and misleading therapeutic claims in the presence of, and in association with, an article after shipment in interstate commerce, results in the article being misbranded in violation of § 301 (k) of the act.

"The Federal Food, Drug, and Cosmetic Act, so far as material, provides:

Sec. 201. For the purposes of this Act—* * *
(m) The term 'labeling' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.
Sec. 301. The following Acts and the causing thereof are * * * prohibited:
(a) The introduction or delivery for introduction into interstate commerce of any * * * drug, * * * that is * * * misbranded.
(b) The * * * misbranding of any * * * drug * * * in interstate commerce.
(k) The alteration, * * * of * * * any part of the labeling of, or the doing of any other act with respect to a * * * drug * * * if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded.
Sec. 502. A drug or device shall be deemed to be misbranded—
(a) If its labeling is false or misleading in any particular.

"In the District Court counsel for plaintiff contended that the phrase 'accompanying such article' means that misbranding occurs through any device which causes printed matter containing false therapeutic claims to be shipped through interstate commerce, including printed matter shipped separately from the product, and constitutes a violation of § 201 (m) if at the destination it becomes associated with and is used in proximity to the transported product on the shelves and display counters of the defendant's agents and distributors.

"The District Court, however, was of the opinion that literature 'placed on the shelves, display counters, or in window displays' was advertising within the meaning of the Federal Trade Commission Act, 15 U. S. C. A. § 55, providing that '"false advertisement" means an advertisement, other than labeling,' and consequently was not a misbranding of an article in interstate commerce.

"Section 8 of the Food and Drugs Act of 1906 provided that the term 'misbranded' should apply to all drugs or articles of food the package or label of which bore any statement, design, or device regarding such article, which was false or misleading in any particular, 21 U. S. C. A. § 9. In interpreting this section, it was held that a circular *enclosed* with an article inside the carton in which it was offered for sale was not within the purview of this section, *U. S.* v. *American etc.*, 186 F. 387. Thereafter, in 1912, the act was amended, specificaly extending the definition to include statements, designs, and devices *contained* in the package, 'to hit precisely the case of circulars or printed matter placed inside the package.' *Seven Cases* v. *United States*, 239 U. S. 510, 515. The act was again amended in 1938 so as to include within the term 'labeling,' all 'labels,' and 'other written, printed, or graphic matter * * * accompanying such article.'

"We have not had the benefit of a brief on behalf of the defendant, but in the District Court the defendant contended that the word 'accompanying' did not include literature which did not go along with the product—in other words, that the test was not nearness, concurrence of display, or availability for reading. With this contention we cannot agree.

"The word 'accompany' is not defined in the act, but we observe that among the meanings attributed to the word are 'to go along with,' 'to go with or attend as a companion or associate,' and 'to occur in association with,' Webster's New International Dictionary (2d edition). There can be no question that among the usual characteristics of labeling is that of informing a purchaser of the uses of an article to which the labeling relates, and that the basic character of the Federal Food, Drug, and Cosmetic Act is not directly concerned with the sale of the products therein described, or whether the literature is carried away by the purchaser. It was enacted to protect the public health and to prevent fraud, and it ought to be given a liberal construction. Consequently, we are impelled to the conclusion that misbranding is cognizable under the act if it occurs while the articles are being held for sale.

"This conclusion is sustained by the legislative history of the act, from which it appears that it was not the purpose of Congress to limit the scope of the phrase 'accompanying such articles' to printed matter placed in the carton in which the article is contained. See Senate Report 1944, 73d Cong., 1st and 2d Sessions, and Senate Report No. 493 of the Committee on Commerce, 73d Cong., 2d Session.

"Our conclusion is also sustained by the decision in the case of *U. S.* v. *Research Laboratories*, 126 F. (2) 42, decided after the District Court had dismissed the complaint in the instant case. The defendant in the *Research* case contended that the circulars constituted advertising and did not constitute labeling within the meaning of the act. In disposing of the contention, the court said, p. 45:

> The contention assumes that printed matter (such as a circular) cannot constitute both advertising and labeling. The assumption is unwarranted. Most, if not all, labeling is advertising. The term 'labeling' is defined in the Act as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising.

"The court also said:

> * * * nor is it material, whether the packages and the circulars did or did not travel in the same crate, carton or other container or on the same train, truck or other vehicle during their interstate journey. The packages and the circulars had a common origin and a common destination and arrived at their destination simultaneously. Clearly, therefore, they accompanied each other, regardless of whether, physically, they were together or apart during their journey.

"The decree of the District Court is reversed, and the cause is remanded for further proceedings in conformity with this opinion."

On December 31, 1942, judgment was entered that the defendant, Royal Lee, individually, and trading as the Vitamin Products Co., or otherwise, its successors or assigns, agents, distributors, servants and all other persons acting on his behalf be perpetually enjoined and restrained as follows: From introducing or delivering for introduction into interstate commerce any food or drug that is misbranded by reason of any false or misleading therapeutic or curative claims for it in the treatment, mitigation, cure, or prevention of human ailments or diseases, such claims appearing either upon the label or labeling, or in literature accompanying the article; for misbranding any food or drug in interstate commerce that is held for sale after shipment in interstate commerce by or through the use of written, printed, or graphic matter containing false or misleading therapeutic or curative claims for the article, i. e., the display or presentation of such written, printed, or graphic matter in the proximity of, or in company

with, such article so as to create in the mind of the purchaser or prospective purchaser a false or misleading impression or belief in regard to the therapeutic or curative value of such article in the treatment of human ailments or diseases, and from doing or performing any acts for the purpose, or which has the effect of evading the foregoing prohibition.

822. Misbranding of Clearwater's Combination Medicine. U. S. v. Henry P. Clearwater (H. P. Clearwater and Pope Laboratories). Plea of nolo contendere. Fine, $150. (F. D. C. No. 5574. Sample Nos. 24345-E, 26965-E.)

On March 17, 1942, the United States attorney for the District of Maine filed an information against Henry P. Clearwater, trading as H. P. Clearwater and Pope Laboratories, Hallowell, Maine, alleging shipment on or about July 18 and August 12, 1940, from the State of Maine into the States of Pennsylvania and Washington of quantities of Clearwater's Combination Medicine which was misbranded.

The combination consisted of three products. Analysis showed that No. 1 was a pink pill consisting essentially of ferrous carbonate, potassium iodide, calcium glycerophosphate, manganese dioxide, sulfur, and a compound of zinc; that No. 2 was a white tablet containing cascara; and that No. 3 was a pink compressed tablet consisting largely of aspirin and starch.

The article was alleged to be misbranded in that certain statements in the labeling which represented and suggested that it would be efficacious as a reconstructive systemic tonic and would be efficacious in the treatment and prevention of rheumatism and arthritis were false and misleading since it would not be efficacious for such purposes.

On July 16, 1942, the defendant entered a plea of nolo contendere and the court imposed a fine of $150.

823. Misbranding of Blue Ridge Mountain Mineral. U. S. v. Robert T. Sides (C. S. & W. Mineral Co.). Plea of nolo contendere. Fine, $200 and probation for 2 years. (F. D. C. No. 6424. Sample No. 37792-E.)

On April 21, 1942, the United States attorney for the Middle District of North Carolina filed an information against Robert T. Sides, trading as the C. S. & W. Mineral Co., Kannapolis, N. C., alleging shipment on or about February 21, 1941, from the State of North Carolina into the State of South Carolina of a quantity of Blue Ridge Mountain Mineral which was misbranded.

Examination of the article showed that it consisted of a natural mineral which when prepared according to directions on the label, consisted essentially of a dilute solution of ferric sulfate with minute amounts of sulfates of other minerals and some ferric hydroxide in suspension.

The article was alleged to be misbranded in that statements in the labeling which represented and suggested that it would be efficacious in the treatment of high blood pressure, pellagra, nervousness, inability to sleep, nervous indigestion, rheumatism, kidney, bladder and stomach trouble, piles, sore eyes, blood poison, all skin infections, erysipelas or tetter, flux, female complaints, irregularities, all blood diseases, loss of appetite, old sores, bed wetting and all skin infections; that it was a powerful germicide and ferruginous tonic, intestinal astringent and internal hemostatic; that it was efficacious in building up new red blood and would promote normal circulation; that it was efficacious in the treatment of gastric indigestion, and would be efficacious as a tonic for blood disorders, indigestion and other forms of stomach trouble and neuritis; that it was efficacious in the treatment of diarrhea and dysentery; and was efficacious in the treatment of boils, carbuncles, skin disease, eczema, leucorrhea or whites, heart trouble and heartburn, and that the user would derive the benefits usually derived from a sojourn at a health resort, were false and misleading since the product would not be efficacious for such purposes.

On October 19, 1942, the defendant having entered a plea of nolo contendere, the court sentenced him to pay a fine of $200, and placed him on probation for a period of 2 years on the general conditions of probation and the additional condition that he was not to sell any more of the product covered by the information.

824. Misbranding of McFadden 3 Sisters Springs mineral water. U. S. v. Roy A. Whipple and Ruth A. Whipple (McFadden 3 Sisters Springs). Pleas of nolo contendere. Imposition of sentence suspended. (F. D. C. No. 4177. Sample No. 15891-E.)

On October 16, 1941, the United States attorney for the Western District of Arkansas filed an information against Roy A. Whipple and Ruth A. Whipple, copartners trading as McFadden 3 Sisters Springs at Hot Springs, Ark., alleging

delivery at Hot Springs, Ark., on or about August 8, 1940, for introduction into interstate commerce from the State of Arkansas into the State of Missouri of a quantity of McFadden 3 Sisters Springs mineral water which was misbranded.

Analysis showed that the article was a lightly mineralized, mildly alkaline water consisting chiefly of calcium and magnesium bicarbonates, sulfates, and chlorides.

The article was alleged to be misbranded in that certain statements in the labeling which represented and suggested that it would be efficacious in the treatment of Bright's disease, diabetes, dropsy, pus in kidney, bladder and urethra, and other kidney, bladder, and urinary troubles, high and low blood pressure, enlarged prostate gland, paralysis, stones in kidney, and other urinary troubles, change of life, female irregularities, insomnia, anemia, nervous prostration, gout and hyperacidity; that it would be efficacious to maintain and restore health in apparently hopeless cases; would rejuvenate shattered nerves and weakened bodies; that it possessed the health-giving properties implied in the statement "Fountains of Health"; would be efficacious in advanced stages of kidney trouble, bladder and gall-stone misery, cystitis, rheumatism, arthritis, sciatica, diabetes, chronic constipation and resulting complications; that it would bring about renewed vitality and fitness; would help nature to discharge toxins which frequently cause serious ills and would flush out accumulated wastes which form poisons to attack the vital organs, the liver, kidney and bladder; that it would be efficacious in cases of faulty elimination and poor assimilation; would assist nature in the cleansing of each tissue, nerve and muscle, thus enabling nature's recreating and rejuvenating forces to carry new life thereto; would be efficacious to control the changes in tissue which produce old age and infirmities, and enable one to catch the rhythm of youth again; and would supply the minerals to keep the body tissues and fluids and organs in perfect running order, clarify the blood, promote physical repair and eliminate waste, were false and misleading since the article would not be efficacious for such purposes.

On September 7, 1942, the defendants entered pleas of nolo contendere and on September 28, 1942, the court suspended imposition of sentence during the period of compliance by the defendants with the Federal Food, Drug, and Cosmetic Act.

825. Misbranding of Cos-Tal Big C. U. S. v. Alvin M. Hitt (Cos-Tal Laboratories Co.). Plea of guilty. Defendant placed on probation for 2 years. (F. D. C. No. 6438. Sample No. 48977–E.)

On June 20, 1942, the United States attorney for the Southern District of Georgia filed an information against Alvin M. Hitt, trading as the Cos-Tal Laboratories Co., at Savannah, Ga., alleging shipment on or about October 7, 1941, from the State of Georgia into the State of South Carolina of a quantity of Cos-Tal Big C, which was misbranded.

Analysis of a sample of the article showed that it was an aqueous emulsion, containing volatile oils, including oil of sandalwood and resins.

The article was alleged to be misbranded in that the statement, "Big C is indicated in cases of un-natural discharges," borne on the bottle label was false and misleading since it represented that the article would be efficacious in the cure, mitigation, treatment or prevention of un-natural discharges, whereas it would not be efficacious for such purposes.

On October 3, 1942, the defendant having entered a plea of guilty, the court placed him on probation for a period of 2 years.

826. Misbranding of Heilmann's Formula "99." U. S. v. Frank J. Heilmann (Heilmann's National Distributors). Plea of guilty. Fine, $50. (F. D. C. No. 7236. Sample No. 60896–E.)

On June 15, 1942, the United States attorney for the Southern District of California filed an information against Frank J. Heilmann, trading as Heilmann's National Distributors at Los Angeles, Calif., alleging shipment on or about August 7, 1941, from the State of California into the State of Oregon of a quantity of Heilmann's Formula "99" which was misbranded.

Analysis of a sample of the article showed that it consisted essentially of potassium acetate, potassium iodide, resinous matter, colchicine, alcohol, and water.

It was alleged to be misbranded in that statements in the labeling which represented and suggested that it would act as a stimulant diuretic to the kidneys; would increase the flow of urine and produce a beneficial effect in gouty conditions; would prevent heart injury resulting from the pain, discomfort and ill

effects of gouty and rheumatic conditions; would be efficacious in the cure, mitigation, treatment, or prevention of rheumatism, articular acute rheumatism, arthritis, neuritis, sciatica, and neuralgia including facial, bronchial, anemic, diabetic, gouty, malarial, and syphilitic neuralgia; would prevent and give immediate relief from pain; would fortify the system against the recurrence of lumbago; would produce buoyant energy, pleasure in living and working, a keen appetite, and soundless sleep; and would strike at the cause of disease and thereby produce immediate benefit, were false and misleading since it would not be efficacious for such purposes.

On July 6, 1942, the defendant entered a plea of guilty and the court imposed a fine of $50.

827. Misbranding of Malitrate F–1. U. S. v. Organic Laboratories, Inc. and W. Warren Walters. Pleas of guilty. Imposition of sentence suspended and defendants placed on probation for 1 year. (F. D. C. No. 7653. Sample No. 84838–E.)

On August 24, 1942, the United States attorney for the Southern District of California filed an information against Organic Laboratories, Inc., Los Angeles, Calif., and W. Warren Walters, alleging shipment on or about December 8, 1941, from the State of California into the State of New York of a quantity of Malitrate F–1 which was misbranded.

Analysis of a sample of the article showed that it was concentrated apple juice.

The article was alleged to be misbranded in that the statements in the labeling which represented and suggested that the article was efficacious in the cure, mitigation, treatment, and prevention of disease by reason of the alkalizing properties of its components; that it was efficacious in the cure, mitigation, treatment or prevention of gastro-intestinal disorders, hyperacidity, (acute indigestion) hyperchlorhydria, intestinal toxemia, diarrhea, constipation, and dysentery; that it was efficacious for use in convalescence from acute or chronic febrile diseases and was especially efficacious in the asthenias and wherever an alkalinizing liquid diet was indicated; that it was efficacious in the cure, mitigation, treatment or preventon of post-operative nausea and of nausea due to pregnancy and seasickness, and of colds, influenza, pneumonia, stomach ulcers and obesity; that it was an efficient dietary regulator for undernourished children; that it would have an energizing effect on the tissues and would be efficacious in the cure and treatment of acute or chronic burns and of inflamed mucous membranes; that when administered as directed it was efficacious in the cure, mitigation, treatment, or prevention of mastoid cavities, open abdominal sinuses, and of various types of indolent ulcers; and would be efficacious in the cure, mitigation, treatment or prevention of ulcerated mouths, sore throats and Vincent's angina, and would in such cases, prove much more effective than the standard perborate treatment, were false and misleading, since the article would not be efficacious for such purposes.

On October 22, 1942, pleas of guilty having been entered on behalf of the defendants the court suspended imposition of sentence and placed them on probation for 1 year, the conditions of the probation being that they cooperate with the Food and Drug Administration and obey the instructions of the probation officer.

828. Misbranding of Bafaline Dental Cream and Bafaline Tablets. U. S. v. The Bafaline Laboratories, Inc. Plea of nolo contendere. Fine, $30 on each of 4 counts. Payment suspended on all counts but the first. (F. D. C. No. 6450. Sample Nos. 36272–E, 36273–E, 51554–E, 51555–E.)

On May 13, 1942, the United States attorney for the District of New Hampshire filed an information against the Bafaline Laboratories, Inc., Manchester, N. H., alleging shipment on or about January 7 and July 18, 1941, from the State of New Hampshire into the State of Massachusetts of quantities of Bafaline Dental Cream and Bafaline Tablets which were misbranded.

Analyses of samples of the dental cream showed that it consisted essentially of calcium carbonate, magnesium compounds, soap, sodium borate, sodium benzoate, saccharin, and glycerin, flavored with oils of peppermint and spearmint. It was alleged to be misbranded in that statements in the labeling which represented that it would be efficacious to prevent the formation of tartar and would keep the gums healthy and in a hygienic condition were false and misleading since it would not be efficacious for such purposes.

Analysis of the Bafaline Tablets showed that they consisted essentially of acetylsalicylic acid and caffeine, with indications of the presence of gelsemium. One shipment of the tablets was alleged to be misbranded in that the statements in the labeling which represented and suggested that they would be

efficacious for the relief of all pain, for the relief of colds, and for the relief of discomfort resulting from migraine, earache, neuritis, and rheumatic pains; would act as a restorative on the nervous system after overindulgence; and would produce unexcelled results in quieting racked nerves and upset nervous stomach and all other symptoms that go with the "morning after," were false and misleading since the article would not be efficacious for such purposes. The tablets in the remaining shipment were alleged to be misbranded in that the statements in the labeling that they would stop all pain, would be efficacious in the cure, mitigation, treatment, prevention, or relief of migraine, earache, neuritis, and rheumatic pains, and would be efficacious in the treatment or prevention of prolonged and severe pain and colds, were false and misleading since they would not be efficacious for such purposes. Both lots of tablets were alleged to be misbranded further in that they were fabricated from two or more ingredients and their labeling did not bear the common or usual name of each active ingredient.

On July 17, 1942, a plea of nolo contendere was entered on behalf of the defendant and the court imposed a fine of $30 on each of the 4 counts but suspended payment on each count but the first, on condition that the defendant not be convicted of subsequent violation of the law.

829. Misbranding of Alberty Food, Instant Alberty Food, Alberty's Vegetable Compound, Alberty's Ca-Mo Pellets, Alberty's Phosphate Pellets, Alberty's Lebara Pellets, Alberty's Laxative Blend, Cheno Herb Tea, Cheno Combination Tablets, and Cheno Preparation of Phytolacca Berry Juice. U. S. v. 12 Packages of Alberty's Food (assorted sizes and various packages of similar products). Tried to the court without a jury. Judgment for the Government. Decree of condemnation and destruction. (F. D. C. No. 3707. Sample Nos. 99902–E to 99908–E incl., 99910–E to 99912–E incl.)

On January 27, 1941, the United States attorney for the District of Columbia filed a libel against 12 packages of Alberty's Food, 18 packages of Instant Alberty Food, 3 packages of Alberty's Vegetable Compound Capsules, 5 packages of Alberty's Ca-Mo Pellets, 10 packages of Alberty's Phosphate Pellets, 8 packages of Alberty's Lebara Pellets, 5 packages of Alberty's Laxative Blend, 30 packages of Cheno Herb Tea, 40 packages of Cheno Combination Tablets, and 5 packages of Cheno Preparation of Phytolacca Berry Juice, at Washington, D. C., alleging that the articles were being offered for sale in the District of Columbia at Vita Health Food Company, Washington, D. C.; and charging that they were misbranded.

Analysis of the Alberty Food showed that it consisted essentially of wheat flour with added calcium phosphate, the total calcium phosphate equaling 6.75 percent.

Analysis of the Instant Alberty Food showed that it consisted mainly of dried, partially skimmed milk, with a little ground cereal and approximately 6 percent added calcium phosphate.

Both products were alleged to be misbranded in that representations in the labeling that they were adequate and appropriate treatments for indigestion, scurvy, rickets, eczema, diseases of malnutrition, nervousness, diarrhea, nausea, stomach irritation and other complications, mental deficiency, stunted physical development, decayed teeth, acidity, common aches, dysfunction of the liver, spleen and pancreas, mucous colitis, "run-down" conditions, depleted nervous system, acidosis, toxic conditions arising from inactive liver, excess bronchial secretions, jaundice, gallstones, gastric hyperacidity, ulcerative conditions, stomach distress, malnutrition, malassimilation, irritated inflamed stomach and anemia; that they would be beneficial to the nerves, the tissues and the vital organs, i. e., liver, heart, and spleen; would relieve severe pain of the stomach and other symptoms of upset digestive tract, aid in the healing of broken legs, increase the red blood cells; would provide strength and health; would cause children to be larger and heavier than children of the same age and not as susceptible to the usual children's diseases; would prevent undernourishment, tooth decay, bodily exhaustion, sagging shoulders, paleness, listless expression in children; were adequate and appropriate treatments of neurotic, backward children by improving mentality, disposition and health; would be effective treatments for infant diarrhea, sore buttocks, irritated stomach and intestines, digestive disturbances, pyloric stenosis and marasmus; would prevent calcium deficiency in pregnant women and their unborn offspring, and prevent after-childbirth run-down condition; would promote the formation of hemoglobin, bone tissue; that they possessed healing, health, youth and energy-giving properties; would cause increase in weight, vitality and strength, clear the skin, and facili-

tate health, long life and youthful appearance; would produce an invigorating effect which would result in strength and stamina, sparkling eyes, pep, clear skin and vigorous health, improving the personal appearance, changing the physique and personality from a negative to a positive type; would make the individual feel strong, feel better physically and produce solid flesh; would revive normal functioning of the body, eliminate the "fixed" toxic poisons, and awaken vital organs and assimilative cells; would increase the peristaltic activities of the sluggish stomach and intestines and normalize digestive juices; would increase assimilation of the calcium element by furnishing materials for increased hemoglobin; would aid in growing strong and good teeth; that they were body-builders, especially in youth; that they would strengthen, rebuild, and facilitate the production of new cells, would prevent physical deterioration, premature old age, ill health and premature death, were false and misleading since the articles would not be efficacious for such purposes.

Analysis of the Alberty's Vegetable Compound Capsules showed that they contained approximately 9½ grains of a mixture of dried vegetables, including tomatoes, beet leaf, spinach, cauliflower and lettuce. Total mineral constituents 1.2 grains per capsule, total calcium (calculated as calcium oxide) 0.12 grain, total phosphorus (calculated as phosphorus pentoxide) 0.01 grain per capsule.

The article was alleged to be misbranded in that certain statements in the labeling, which represented that it would supply mineral elements and nourishment, which would enhance the powers of digestion so that the natural resistance of the body would not be lowered and the starch and sugar intake would be kept at a minimum, and that it would increase strength and energy, were false and misleading since it would not be efficacious for such purposes.

Analysis of the Ca-Mo Pellets showed that they consisted of approximately $\frac{1}{1000}$ grain of calcium phosphate and 1 grain of milk sugar moulded into pellet form.

It was alleged to be misbranded in that representations in the labeling, that it would build up the calcium reserve, offset acidity, sweeten the over-acid stomach, and that it was an adequate and appropriate treatment for eczema, were false and misleading since it would not be efficacious for such purposes.

Analysis of the Alberty's Phosphate Pellets showed that they consisted of minute amounts of iron, potassium, sodium, calcium, and magnesium phosphates moulded into pellet form with milk sugar.

The article was alleged to be misbranded in that representations in the labeling that it was an adequate and appropriate treatment for nervous conditions, nervousness, neurasthenia, nervous debility, weakness, sleeplessness, nervous breakdown and dysfunction of the endocrine glands; that it was a preventive of constipation, loss of stamina, mental and physical exhaustion, loss of memory, sleeplessness, high blood pressure symptoms, loss of energy, despondency, and trembling or aching limbs; that it would promote digestion, absorption and assimilation of food, provide nerve force, induce restful sleep and renew strength and vitality, would promote better digestion and assimilation, and produce a soothing, beneficial effect on the nerve tissues of nervous, high strung, mentally and physically exhausted persons, would improve the force, tone, and vigor of the nervous tissues, and act as a tonic to the blood and the entire body, were false and misleading since the article would not be efficacious for such purposes.

Analysis of the Lebara Pellets showed that they consisted of approximately $\frac{1}{1000}$ grain of anhydrous sodium sulfate and 1 grain of milk sugar moulded into tablet form.

The article was alleged to be misbranded in that representations in the labeling that it would increase the flow of bile, keep the skin and complexion clear, that it was a diuretic, and that it was an adequate and appropriate treatment for biliousness, headache, bad taste in the mouth, coated tongue, spots before the eyes, bearing down pains in the small of the back and constipation of hepatic origin, were false and misleading since the article would not be efficacious for such purposes.

Analysis of the Alberty's Laxative Blend showed that it consisted of a mixture of plant drugs including buchu leaves, uva ursi leaves, sassafras bark, couch grass, elderberry flowers, horsetail, yarrow flowers, fennel seed, marshmallow root, senna leaves, aniseed and buckthorn bark.

It was alleged to be misbranded in that representations in the labeling that it was an aid to digestion, a tonic laxative, and would relieve the usual feeling of depletion following evacuation, were false and misleading since it would not be efficacious for such purposes.

Analysis of Cheno Herb Tea showed that it consisted of a mixture of plant drugs, including senna leaves, sassafras bark, licorice root, seaweed, caraway seed, mint leaves, fennel seed, and aniseed.

Analysis of the Cheno Combination Tablets showed that they contained dried okra, Irish moss, dulse, green leafy material, such as parsley, spinach and celery, and 1.7 grains per tablet of calcium phosphate. The total iron content was 0.0004 grain; total iodine 0.0001 grain per tablet.

Analysis of the Cheno Preparation of Phytolacca Berry Juice showed that it consisted of a plant extract such as poke berry juice in a mixture of water, sugar, and alcohol.

The Cheno preparations were alleged to be misbranded in that representations in the labeling that the articles constituted adequate and appropriate treatment for disturbances of nutrition, overweight, underweight, leanness, obesity, stomach disorders, bronchial colds, hypothyroidism with dry skin, lack of perspiration, heart disturbances, constipation, mental sluggishness, slow movement, lack of activity, asthma, hay fever, and sensitiveness to various kinds of food, headache, dizziness, fatigue, drowsiness, sleepiness; that it would be an efficacious treatment for pancreatic, hypo-gonodal, thyroid and pituitary obesity, would improve health, reduce nervousness, provide buoyancy of spirit and freedom from logy oppressiveness, promote firm flesh and soft skin with fine texture, overcome lassitude, prevent and reduce the storage of excess fat, prevent toxemia, regulate the elasticity of the muscles, balance and regulate body functions, speed up metabolism, eliminate accumulated water in cells and tissues, increase energy and vitality and remineralize the body, were false and misleading since the articles would not be efficacious for such purposes.

On April 7, 1941, Ada J. Alberty, Los Angeles, Calif., claimant, having filed a motion that the action be transferred to a district in close proximity to the Southern District of California, an order was entered in the District Court for the District of Columbia transferring the action to the Northern District of California, Southern Division; and ordering that the clerk forward all files and records of the case to that district for trial. The case came on for trial before the court on January 22, 1942, and was continued to January 23. A recess was ordered until February 7, 1942, on which date the trial was resumed and was concluded on February 8, 1942. The court took the case under advisement and on June 29, 1942, handed down a decision for the Government and on October 26, 1942, made the following findings of fact and conclusions of law:

Norcross, *District Judge.* "The above-entitled cause having been regularly tried without a jury and having been submitted by the parties hereto; Frank J. Hennessy, Esquire, United States attorney for the Northern District of California, and A. J. Zirpoli, Esquire, assistant United States attorney for said district, appearing as counsel for libelant, and Eldon V. Soper, Esquire, and Francis W. Murphy, Esquire, appearing as counsel for the claimant; and evidence both oral and documentary having been introduced, and the court being fully advised in the premises, now makes its findings of fact and conclusions of law as follows:

FINDINGS OF FACT

I.

"That the allegations of the libel are true.

II.

"That the allegations of paragraph third of the answer of claimant and paragraphs II and IV of the amended answer of claimant are not true.

III.

"That the 'Modified Order to Cease and Desist' entered by the Federal Trade Commission on June 26, 1939, in the matter of 'Adah Alberty, etc., docket number 2875,' pertains to and relates to a matter and matters and things separate and distinct from the proceedings in the instant case and does not involve the articles of drug held and offered for sale in the District of Columbia in the manner recited in the libel herein.

IV.

"That the following articles described in said libel

'12 packages, more or less, of Alberty Food (Assorted sizes),
18 packages, more or less, of Instant Alberty Food (assorted sizes),
33 packages, more or less, of Alberty's Vegetable Compound Capsules,
5 packages, more or less, of Alberty's Ca-Mo Pellets,
10 packages, more or less, of Alberty's Phosphate Pellets,
8 packages, more or less, of Alberty's Lebara Pellets,
5 packages, more or less, of Alberty's Laxative Blend,
30 packages, more or less, of Cheno Herb Tea,
40 packages, more or less, of Cheno Combination Tablets, and
5 packages, more or less, of Cheno Preparation of Phytolacca Berry Juice.'

were being offered for sale in the District of Columbia at the time of the filing of the libel herein.

V.

"That the said articles described in the paragraph immediately above were held in and intended for sale in the District of Columbia at the time and place aforesaid.

VI.

"That the said articles described in paragraph IV of these findings of fact were misbranded at the time of the filing of the libel herein, in the manner following:

"352 (a) in that the statements and designs appearing in the labeling (booklet 'Calcium The Staff of Life'), as set forth in Exhibit 'A', attached to the libel, are false and misleading in that they represent that the articles are efficacious for the purposes recommended, whereas the articles are not efficacious for the purposes recommended; (Alberty Food and Instant Alberty Food)

"352 (a) in that the following statements appearing in the labeling (booklet 'Calcium The Staff of Life') are false and misleading in that they represent that the article is efficacious for the purposes recommended, whereas the article is not efficacious for the purposes recommended: (Alberty's Vegetable Compound Capsules)

'WHEN THE DIET MUST BE STARCH AND SUGAR FREE

'There are times when persons suffering from malfunctions of certain organs are unable to tolerate starch and sugar in the same proportion as the normal individual. Physicians then recommend a diet as free from starch and sugar as it is possible to get and still give the person enough nourishment to maintain the life and health.

'During such dietary regimes it is absolutely necessary to keep the digestive functions working at their best because nature MUST get all the nourishment possible from what food is eaten without in any way increasing the load of sugar or starch.

'ALBERTY VEGETABLE COMPOUND CAPSULES give an easily digestible form of organic minerals. ***ALBERTY FOOD, VEGETABLE COMPOUND CAPSULES AND OXORIN TABLETS, furnish mineral elements, nourishment and enhance the powers of digestion so that the natural resistance of the body is not lowered and the starch and sugar intake is still kept at a minimum.

'Reports of many users of ALBERTY VEGETABLE COMPOUND CAPSULES, OXORIN tablets and ALBERTY FOOD show that they have acquired greater sugar and starch tolerance and an increase in strength and energy.'

"352 (a) in that the following statements appearing in the labeling (booklet 'Calcium The Staff of Life', pp. 42 and 47) are false and misleading in that they represent that the article is efficacious for the purposes recommended, whereas the article is not efficacious for the purposes recommended: (Alberty's Ca-Mo Pellets)

'* * * .The following formulas comprise ingredients of homeopathic dosage and under those principles are credited with the action described.

'CA–MO helps to build up a calcium reserve. Its calcium content offsets acidity, sweetening the over-acid stomach.

'ECZEMA

'Improper diet is frequently the cause. * * *

'Here is the treatment I have seen used quiet frequently by physicians: Cleanse the affected parts * * *. Pat dry and then anoint with * * * salve * * *. A prescription, identical with which I now call CA-MO PELLETS, was given every two hours during the day. * * *'

"352 (a) in that the statements appearing in the labeling (booklet 'Calcium The Staff of Life'), as set forth in Exhibit 'B,' are false and misleading in that they represent that the article is efficacious for the purposes recommended, whereas the article is not efficacious for the purposes recommended; (Alberty's Phosphate Pellets.)

"352 (a) in that the following statements appearing in the labeling (booklet 'Calcium The Staff of Life,' pp. 42 and 49) are false and misleading in that they represent that the article is efficacious for the purposes recommended, whereas the article is not efficacious for the purposes recommended: (Alberty's Lebara Pellets.)

'The following formulas comprise ingredients of homeopathic dosage and under those principles are credited with the action described. * * *

'ALBERTY LEBRARA PELLETS * * * contain salts which act to increase the flow of bile from the liver * * * An active liver keeps the skin and complexion clear, there is none of the yellow, bilious look characteristic of the toxic condition resulting from a dormant liver.

'HOW TO HELP THE LIVER

'LEBRARA PELLETS contain a valuable salt which has a definite reaction on the liver and as a diuretic, by increasing the flow of bile. LEBRARA PELLETS act as a bile stimulant in hepatic disturbances characterized as biliousness, headache, bad taste in the mouth, coated tongue, spots before the eyes, bearing down pains in the small of the back and constipation of hepatic origin.'

"352 (a) in that the following statements (booklet 'Calcium The Staff of Life,' p. 52) are false and misleading in that they represent that the article is efficacious for the purposes recommended, whereas the article is not efficacious for the purposes recommended: (Alberty's Laxative Blend.)

'ALBERTY'S LAXATIVE BLEND includes seventeen herbs which, according to botanical books, were one of the best combinations obtainable for a tonic laxative. Herbs are included which have a tonic after-effect, that relieves the usual feeling of depletion following evacuation of the bowels from ordinary artificial laxatives.

'For the temporarily constipated person it acts * * * to * * * aid digestion.'

"352 (a) in that the statement upon a placard accompanying the articles Reduce the Cheno Way. The Five Factor Plan. Safe Scientific is false and misleading in that it represents that the articles are efficacious for the purposes recommended, whereas the articles are not efficacious for the purposes recommended; (Cheno Herb Tea, Cheno Combination Tablets, Cheno Preparation of Phytolacca Berry Juice.)

"352 (a) in that the statements and designs appearing in the labeling (booklet Cheno Plan The 5 Factor Reducing System), as set forth in Exhibit C, attached to the libel, are false and misleading in that they represent that the articles are efficacious for the purposes recommended, whereas the articles are not efficacious for the purposes recommended; (Cheno Herb Tea, Cheno Combination Tablets, Cheno Preparation of Phytolacca Berry Juice.)

VII.

"That the booklets Calcium The Staff of Life and Cheno Plan the 5 Factor Reducing System and the placard Reduce the Cheno Way—The Five Factor Plan, Safe, Scientific accompanied the articles described in paragraph IV hereof at the time and place described in paragraph IV hereof and then and there constituted part of the labeling of the aforesaid articles.

CONCLUSIONS OF LAW

I.

"That the articles described in the libel herein and paragraph IV of the above findings of fact were drugs illegally offered for sale and held and intended for sale within the District of Columbia at the time of the filing of the libel herein, in violation of Section 534 of Title 21 USCA, for the reason that said articles were at said time and place misbranded within the provisions of Section 352 (a) of Title 21 USCA.

II.

"That the booklets Calcium The Staff of Life and Cheno Plan the 5 Factor Reducing System and the placard Reduce the Cheno Way. The Five Factor Plan. Safe. Scientific accompanied the articles described in paragraph IV of the above findings of fact at the time and place described in paragarph IV of the above findings of fact and then and there constituted part of the labeling of the aforesaid articles.

III.

"That the Modified Order to Cease and Desist entered by the Federal Trade Commission on June 26, 1939, in the matter of Adah Alberty, etc., Docket No. 2875, is not res judicata to the matters and things alleged in the libel herein and does not estop the libelant herein to allege, assert or maintain that the matters and things in the libel herein constitute labeling within the provisions of 21 USC 352 (a) and does not estop libelant to allege, assert or maintain that the matters and things in the libel herein, alleged to consist of booklets and placards, accompanied the articles in said libel specifically described.

IV.

"That the above-mentioned articles of drugs described in paragraph IV of the findings of fact above, be, and they are hereby, condemned and forfeited to the United States, to be by the United States of America destroyed forthwith.

On October 26, 1942, judgment of condemnation was entered and it was ordered that the product be destroyed and that the clerk of court return the file and record and copy of the decree of condemnation and destruction to the clerk of the United States Court for the District of Columbia, with directions that a certified copy of the decree be furnished the marshal.

On November 7, 1942, the claimant filed a motion for a new trial, which motion was denied by the court February 13, 1943, without opinion.

830. Misbranding of Ecco Hygienic Powder. U. S. v. 501 Bottles of Ecco Hygienic Powder. Default decree of condemnation and destruction. (F. D. C. No. 7636. Sample No. 80612–E.)

On June 15, 1942, the United States attorney for the Southern District of Ohio filed a libel against 501 bottles of the above-named product at Dayton, Ohio, which had been shipped on or about April 13, 1942, alleging that the article had been shipped in interstate commerce by the Eby Chemical Co. from Harrisburg, Pa.

Analysis showed that the article consisted essentially of boric acid and alum together with small quantities of oxyquinoline sulfate, menthol, thymol, phenol, eucalyptol, salicylic acid, and methyl salicylate. Bacteriological tests showed that it was not germicidal in the dilution recommended for use.

The article was alleged to be misbranded: (1) In that the statements in the labeling which represented and suggested that it was a reliable contraceptive, that it was an appropriate treatment for head colds, rhinitis, rectal irritations, bleeding gums, trench mouth, sore throat, tonsillitis, quinsy, laryngitis, sinusitis, pyorrhea, chickenpox, congestion, measles, infected wounds, abscesses, boils, hemorrhoids, vaginal burns, leucorrhea, vaginitis, and gonorrhea; and that it was an adequate treatment for such skin conditions as dandruff, itchy scalp, sores, impetigo, hives, corns, callouses, bunions, acne, blackheads, bed sores, barber's itch, cold sores, eczema, fever blisters, frost bite, chilblains, poison ivy, skin rash and sunburn, were false and misleading since it would not be efficacious for such purposes; (2) in that the following statements on the label, "Ecco Powder is a concentrated inhibitory antiseptic, efficient and economical. Always use fresh solutions properly diluted with hot or boiling water * * * When possible use wet dressing or cover affected parts with clean sterile bandage or gauze after dusting with Ecco Powder" were misleading since they failed to reveal the material fact that it was not antiseptic except when used as a wet dressing or with a bandage that would permit prolonged contact with the body.

On July 16, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

831. Misbranding of mercurochrome. U. S. v. 60 Dozen Bottles of Mercurochrome. Default decree of condemnation and destruction. (F. D. C. No. 7841. Sample No. 78842–E.)

On June 30, 1942, the United States attorney for the Western District of Pennsylvania filed a libel against 60 dozen bottles of mercurochrome at Pittsburgh, Pa., alleging that the article had been shipped in interstate commerce on or about April 9, 1942, by the Certified Pharmacal Co., Inc., from New York, N. Y.; and charging that it was misbranded in that the statement "Contents 9 cc.," borne on the label was false and misleading as applied to an article in bottles containing less than 9 cubic centimeters.

On August 10, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

832. Misbranding of Epsom salt. U. S. v. 130 Packages of Epsom Salt. Default decree of condemnation and destruction. (F. D. C. No. 7990. Sample No. 19481–F.)

The packages of this product contained a smaller amount than declared on the label.

On July 28, 1942, the United States attorney for the District of New Hampshire filed a libel against 130 packages of Epsom salt at Concord, N. H., alleging that the article had been shipped in interstate commerce on or about June 30, 1942, by the Allied Salt & Chemical Co., from Boston, Mass.; and charging that it was misbranded in that the statement "Five Pounds" borne on the carton was false and misleading as applied to an article that was short weight. The article was labeled in part: "Five Pounds * * * Epsom Salt."

On September 8, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

833. Misbranding of Faunce's Tooth Paste. U. S. v. 30 Packages of Faunce's Tooth Paste. Default decree of condemnation and destruction. (F. D. C. No. 7843. Sample No. 77051–E.)

On June 30, 1942, the United States attorney for the Eastern District of Pennsylvania filed a libel against 30 packages of Faunce's Tooth Paste at Philadelphia, Pa., alleging that the article had been shipped in interstate commerce on or about June 9, 1942, by Benjamin R. Faunce, from Riverside, N. J.

Analysis of a sample of the article showed that it consisted essentially of calcium carbonate, salt, glycerine, and material derived from bile, flavored with peppermint.

The article was alleged to be misbranded in that statements in the labeling which represented and suggested that the article would be efficacious in the treatment of pyorrhea-bleeding gums, bad odor, tartar, and discoloration, and would act as a prophylactic pus solvent, were false and misleading since it was not effective for such purposes and would not act as a prophylactic pus solvent.

On August 3, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

834. Misbranding of Hanford's Balsam of Myrrh. U. S. v. 22 Packages of Hanford's Balsam of Myrrh. Default decree of condemnation and destruction. (F. D. C. No. 7888. Sample No. 70592–E.)

On July 15, 1942, the United States attorney for the Southern District of Florida filed a libel against 22 packages of Hanford's Balsam of Myrrh, at Jacksonville, Fla., alleging that the article had been shipped in interstate commerce on or about April 11 and May 14, 1942, by G. C. Hanford Mfg. Co., from Syracuse, N. Y.

Analysis of a sample of the article showed that it consisted essentially of alcohol, water, myrrh, benzoin, and chlorthymol.

The article was alleged to be misbranded in that certain statements on the bottle label, carton, and accompanying circular which represented and suggested that it would be efficacious for sprained ankle, caked udder, and swellings; would be effective for preventing sunburn; would be effective in the treatment of frostbites, athlete's foot and minor skin irritations; would be effective as a soothing application for bunions; would be effective when used as eardrops; and when other treatments failed would be effective for cuts, lacerations, and bruises, and for horses badly galled or calked; that it possessed remarkable soreness removing qualities and would heal without leaving a scar, were false and misleading since it would not be effective for the purposes claimed, did not possess remarkable soreness removing qualities and would not heal without leaving a scar.

On August 28, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

835. Misbranding of Menestrex. U. S. v. 11 Bottles of Menestrex. Default decree of condemnation and destruction. (F. D. C. No. 7896. Sample No. 71562–E.)

On July 17, 1942, the United States attorney for the Western District of Kentucky filed a libel against 11 bottles of Menestrex at Paducah, Ky., alleging that the article had been shipped in interstate commerce on or about December 22, 1941, by the Rex Laboratory, from Nashville, Tenn.

Analysis of a sample of the article showed that it contained 3.43 grains of quinine sulfate and 0.35 grain of potassium permanganate per capsule.

The article was alleged to be misbranded in that certain statements in the labeling which represented and suggested that it was an effective treatment for painful, scanty, or functionally delayed menstruation and was a scientific preparation, were false and misleading since it would not be an effective treatment for such conditions and was not a scientific preparation.

On September 15, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

836. Misbranding of Pine Glow Bath and Rainbo Bath. U. S. v. 291 Bottles of Pine Glow Bath and 261 Bottles of Rainbo Bath. Default decree of condemnation and destruction. (F. D. C. No. 7881. Samples Nos. 95124–E, 95125–E.)

On July 14, 1942, the United States attorney for the District of Nevada filed a libel against the above named products at Reno, Nev., alleging that the articles had been shipped in interstate commerce on or about February 16, 1942, by the Rainbobath Laboratories from San Francisco, Calif.

Analysis of the Pine Glow Bath showed that it consisted essentially of water, the sodium salt of a sulfonated oil, and volatile oils, including oil of pine needles. Analysis of a sample of the Rainbo Bath showed that it was essentially a lime-sulfur solution.

The Pine Glow Bath was alleged to be misbranded in that certain statements in the labeling were false and misleading since they represented and suggested that the article when placed in the bath water would be efficacious in overcoming insomnia and was an aid to health and would be efficacious for muscular rheumatism and gout and for eliminating toxic poisons and for toning up the circulatory and nervous systems; would be efficacious in the treatment of the skin and complexion; would increase the white corpuscles in the blood and cause toxins and other impurities to pass out through the pores of the skin and would benefit the entire respiratory tract and would be efficacious for weight reduction, whereas it would not be effective for such purposes.

The Rainbo Bath was alleged to be misbranded in that certain statements in the labeling were false and misleading since they represented and suggested that the article was colloidal sulfur, that when placed in the bath water the user would obtain the benefits derived from the treatments given at hot springs and spas, and that it would be efficacious in the treatment in the diseases, conditions, and symptoms mentioned and described in the labeling, and would be efficacious for reducing, whereas, in truth and in fact, it was not a colloidal sulfur, and it would not be efficacious or useful for the purposes and in the manner stated, represented and suggested in the labeling.

On August 3, 1942, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

837. Misbranding of Bi-Sal Tablets. U. S. v. 129 Bottles of Bi-Sal Tablets. Default decree of condemnation and destruction. (F. D. C. No. 7783. Sample No. 91809–E.)

On July 7, 1942, the United States attorney for the Northern District of Texas filed a libel against 129 bottles of Bi-Sal tablets at Dallas, Texas, alleging that the article had been shipped in interstate commerce on or about April 7, 1942, by the Oxford Products, Inc., from Cleveland, Ohio.

Analysis of a sample of the article showed that the tablets contained phenolphthalein (½ grain per tablet) extracts of plant drugs, including nux vomica and a laxative drug, and an extract of bile.

The article was alleged to be misbranded (1) in that the name "Panogestic Enzymes with Bile Salts Compound" was misleading since it was essentially a laxative and its physiologic activity was due principally to phenolphthalein, which is neither an enzyme nor a bile constituent but is a coal tar derivative; (2) in that the statement on the carton "This Combination is used * * * in certain forms of Gall Bladder and Bile Dust Infections," was false and misleading, since it represented and suggested that the article would be effective in the treatment of gall bladder and bile dust infection, whereas it was not

so effective; and (3) in that the labeling failed to bear adequate directions for use, since the directions appearing upon the labeling "2 Tablets about 2 hours after Breakfast and 2 Tablets at bedtime" and "To avoid the 'Laxative Habit' do not take continously," failed to specify that a laxative should be taken only occasionally when needed.

On August 24, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

838. Misbranding of Ironized Yeast. U. S. v. 500 Cartons of Ironized Yeast. Consent decree of condemnation. Product ordered released under bond to be brought into compliance with the law. (F. D. C. No. 6512. Sample No. 74949–E.)

On December 20, 1941, the United States attorney for the Southern District of New York, filed a libel against 500 Cartons of Ironized Yeast, at New York, N. Y., alleging that the article had been shipped in interstate commerce by the Ironized Yeast Co., Inc., from Atlanta, Ga.; and charging that it was misbranded. The article was labeled in part: "Each tablet contains reduced iron—Iron Peptonized Haemoglobin Vitamin B Concentrate from Yeast Lager Yeast."

The article was alleged to be misbranded in that certain statements in the labeling which represented that it would be efficacious for underweight, thin, run-down, tired and nervous people were false and misleading since they held out the promise and created the impression that consumption of the article as directed would result in gain of weight, increased vigor and appetite, and the disappearance of tiredness and nervousness, whereas the article when used as directed would not increase weight, overcome nervousness, produce vigor, improve the appetite, produce charm and popularity, or otherwise accomplish the results promised, implied, and represented.

On October 26, 1942, the Ironized Yeast Co., Inc., claimant, having withdrawn its amended answer therefore entered and having consented to the entry of a decree, judgment of condemnation was entered and it was ordered that the product be released under bond conditioned that it be brought into compliance with the law under the supervision of the Food and Drug Administration.

839. Misbranding of Old Hickory Ointment. U. S. v. 52 Jars of Old Hickory Ointment. Default decree of condemnation and destruction. (F. D. C. No. 8019. Sample No. 28503–F.)

On July 31, 1942, the United States attorney for the Northern District of Georgia filed a libel against 52 jars of Old Hickory Ointment at Atlanta, Ga., alleging that the article had been shipped in interstate commerce on or about May 5, 1942, by the Old Hickory Medicine Co., from Chattanooga, Tenn.

Analysis of a sample of the article showed that it consisted essentially of zinc oxide, salicylic acid, calomel, carbolic acid, camphor, menthol, and petrolatum.

The article was alleged to be misbranded in that the following statements on the label: "Acne, Barber's Itch, Tetter, * * * Eczema, Scabies, * * * Dandruff, Psoriasis, Itching Piles," were false and misleading since they represented and suggested that the article would be effective in the treatment of such conditions, whereas it would not be so effective. It was alleged to be misbranded further in that its label failed to bear a statement of the quantity or proportion of calomel, a mercury derivative, present in the article.

On September 22, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS FOR VETERINARY USE

840. Misbranding of Eby's Chicken Medicine and Eby's Swine Medicine. U. S. v. Frank D. Eby (Eby Remedy Co.). Plea of guilty. Fine, $150 and costs. (F. D. C. No. 5580. Sample Nos. 76759–E, 76760–E, 76930–E.)

On September 22, 1942, the United States attorney for the Northern District of Iowa filed an information against Frank D. Eby, trading as Eby Remedy Co., at Marengo, Iowa, alleging shipment on or about December 3, 1941, and January 29, 1942, from the State of Iowa into the State of South Dakota of quantities of Eby's Chicken Medicine and Eby's Swine Medicine which were misbranded.

Analysis of one sample of the Chicken Medicine showed that it consisted essentially of volatile oils including eucalyptol and phenolic compounds, small proportions of benzoic acid, and iodine. Analysis of a second sample showed that it consisted essentially of phenolic and camphoraceous substances including menthol, eucalyptol, and camphor, and small proportions of benzoic acid, water, and an oil-soluble dye. Analysis of a sample of the Swine Medicine

showed that it consisted essentially of phenolic and camphoraceous substances including camphor, eucalyptol, and menthol, and small proportions of benzoic acid, water, and an oil-soluble dye.

The Chicken Medicine was alleged to be misbranded in that the following statements: "Chicken Medicine * * * Separate worst cases. Clean up. After chickens have gone to roost, spray this remedy on their heads for three nights with a small household fly spray," borne on the label, were false and misleading in that they represented that the article would be an effective treatment for sick chickens, whereas it would not. One shipment of the Chicken Medicine was alleged to be misbranded further in that the statements "For Swine Colds Make six small holes in cap of bottle and sprinkle on bedding * * * This remedy has been used by thousands of farmers for twelve years," borne on the label, were false and misleading in that they represented that the article would be efficacious as a treatment of swine colds, whereas it would not be efficacious for such purpose.

One shipment of the Chicken Medicine was alleged to be misbranded further in that it was in package form and the statement of the quantity of the contents which is required by the act to appear on the label was not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices in the labeling) as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

The Swine Medicine was alleged to be misbranded in that the statements "Swine Medicine * * * Clean up. Turn the cap of this bottle over on a board and make six holes with the point of a shingle nail. Replace on bottle and sprinkle on or under bedding. Keep hogs warm and quiet. Keep warm and quiet. Do not disturb if very sick * * * This remedy has been used by thousands of farmers for twelve years," borne on the label, were false and misleading since they represented that the article would be an effective treatment for sick swine, whereas, it would not be effective for such purpose.

On September 22, 1942, the defendant entered a plea of guilty and the court imposed a fine of $150 and costs.

841. Misbranding of Beebe V-V Vim and Vigor. U. S. v. Beebe Laboratories, Inc. Plea of guilty. Fine, $100. (F. D. C. No. 7715. Sample No. 76750–E.)

On September 28, 1942, the United States attorney for the District of Minnesota filed an information against the Beebe Laboratories, Inc., St. Paul, Minn., alleging shipment on or about January 19, 1942, from the State of Minnesota into the State of Wisconsin, of a quantity of Beebe V-V Vim and Vigor, which was misbranded.

Analysis of a sample of the article showed that it consisted of plant material containing essentially, kamala, areco nuts, nux vomica, fenugreek, tobacco, oil of anise, and oil chenopodium.

It was alleged to be misbranded in that the statements, "V-V Vim & Vigor * * * As a Tonic * * * A Flock Treatment for Chickens and Turkeys," borne on the label was false and misleading in that they represented and suggested that the article would be efficacious to promate vim and vigor in poultry, would be efficacious as a tonic for poultry, and would be an efficacious flock treatment for diseases of chickens and turkeys, whereas it would not be efficacious for such purposes.

On September 29, 1942, a plea of guilty having been entered on behalf of the defendant, the court imposed a fine of $100.

842. Misbranding of I-O-Tab (Iotein Tablets). U. S. v. Frank Y. Chuck (Dr. F. Y. Chuck Research Laboratories). Plea of not guilty. Jury trial. Jury unable to reach verdict and discharged. Plea of not guilty withdrawn and plea of nolo contendere entered. Fine, $100. (F. D. C. No. 2895. Sample No. 13373–E.)

On January 14, 1942, the United States attorney for the Northern District of California filed an information against Frank Y. Chuck, trading as Dr. F. Y. Chuck Research Laboratories, San Francisco, Calif., alleging shipment on or about February 29, 1940, from the State of California into the State of Oregon of a quantity of I-O-Tab (Iotein Tablets), which were misbranded.

Analysis of a sample of the article showed that the tablets contained 3.44 percent of nicotine and 0.85 percent of iodine, incorporated in a base of feed concentrate containing 24 percent of crude fat, reducing sugars, wheat starch, and tannic acid.

The article was alleged to be misbranded in that statements in the labeling which represented that it would be efficacious in the treatment of fowl suffering

from coccidiosis, blackhead, and cecum worms (Heterakis gallina); that it would be efficacious in the treatment of pullets, hens, and turkeys that had gone "backward" or "light" due to chronic coccidiosis, blackhead, or cecum worms; that it would have a destructive action on the parasites causing coccidiosis and blackhead and on cecum worms and that it would be efficacious in the treatment of very severe cases of acute and chronic types of coccidiosis, were false and misleading since it would not be efficacious for such purposes.

On May 13, 1941, the defendant having entered a plea of not guilty, the case came on for trial before a jury. The trial was concluded on May 20 and the case was submitted to the jury, which after deliberating announced that it was unable to reach a verdict. The jury was thereupon discharged. The defendant, on December 23, 1941, withdrew his plea of not guilty and entered a plea of nolo contendere, which plea was accepted by the court and a fine of $100 was imposed.

843. Misbranding of Coccidiosis Mash. U. S. v. J. Kendley Martin (Standard Milling Co.). Plea of nolo contendere. Fine, $100. (F. D. C. No. 6445. Sample No. 37913–E.)

On May 20, 1942, the United States attorney for the Northern District of Georgia filed an information against J. Kendley Martin, trading as Standard Milling Co., at Atlanta, Ga. alleging shipment on or about April 15, 1941, from the State of Georgia into the State of North Carolina of a quantity of Coccidiosis Mash which was misbranded.

Analysis of a sample of the article showed that it consisted principally of wheat bran, wheat starch, finely ground yellow corn, a milk sugar by-product, yeast, and corn gluten meal, with smaller amounts of alfalfa leaf meal, meat scraps, soya bean meal, and salt, very little, if any, linseed tissues, and dried buttermilk, and a trace of oat product and peanut hulls.

The article was alleged to be misbranded in that the statements in the labelling which represented and suggested that it would be efficacious in the cure, mitigation, treatment or prevention of coccidiosis, were false and misleading since it would not be efficacious for such purpose.

On September 21, 1942, the defendant entered a plea of nolo contendere and on October 2, 1942, the court imposed a fine of $100.

844. Misbranding of Bovosan. U. S. v. Robert Gisler. Plea of not guilty. Tried to the court. Judgment of guilty on charge of failure to declare active ingredients and not guilty on charges based upon therapeutic claims. (F. D. C. No. 6487. Sample No. 60023–E.)

On April 2, 1942, the United States attorney for the Northern District of California filed an information against Robert Gisler of San Francisco, Calif., alleging shipment on or about December 16, 1940, from the State of California into the State of Oregon of a quantity of Bovosan which was misbranded.

Analysis of a sample of the article showed that it consisted essentially of small porportions of sulfur, phenolic compounds, and soap, incorporated in a base of petrolatum.

It was alleged that the article was misbranded in that statements appearing in the labeling which represented and suggested that it would be efficacious in the treatment of vaginitis and related diseases and that it would be efficacious to prevent infection of a healthy cow by a diseased bull or of a healthy bull by a diseased cow, were false and misleading, since the article would not be efficacious for such purposes. It was alleged to be misbranded further in that it was not designated solely by a name recognized in an official compendium, and was fabricated from two or more ingredients and its label did not bear the common or usual name of each active ingredient.

On May 26, 1942, the defendant having entered a plea of not guilty, the case came on for trial before the court without a jury. The trial having been concluded on May 29, 1942, the court entered judgment that the defendant was guilty on the charge of failure to declare the active ingredients, but was not guilty on the remaining charges. The court reserved sentence and on October 19, 1942, imposed a fine of $10.

845. Misbranding of cleaning powder, Bovostick, Powder No. 1, and Powder No. 2. U. S. v. 26 cans of Cleaning Powder, et al. Default decree of condemnation and destruction. (F. D. C. No. 5615. Sample Nos. 23002–E to 23005–E, incl.)

On September 19, 1942, the United States attorney for the Northern District of California filed a libel against 26 cans containing a product known as "Clean-

ing Powder" and as "Bovosan Powder," 110 articles known as "Bovostick," 1 large can of a product known as "Powder No. 1," and as "Pregnancy Powder," and 2 paper bags containing a powder known as "Powder No. 2," and as "Rinsing Powder," alleging that the articles had been shipped in foreign and interstate commerce from Zug, Switzerland.

The articles, with the exception of Bovostick, were alleged to be misbranded ing that they were drugs in package form and failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; (2) in that they failed to bear labels containing an accurate statement of the quantity of the contents; and (3) in that they were fabricated from two or more ingredients and their labels failed to bear the common or usual name of each active ingredient. The products, including the Bovostick, were alleged to be misbranded in that their labels failed to bear adequate directions for use.

On October 24, 1942, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

846. Misbranding of Near's Garjex Powder. U. S. v. 22 Packages of Near's Garjex Powder. Default decree of condemnation and destruction. (F. D. C. No. 7400. Sample No. 86226–E.)

On May 2, 1942, the United States attorney for the Northern District of Illinois filed a libel against 22 packages of Near's Garjex Powder at Elgin, Ill., alleging that the article had been shipped in interstate commerce on or about February 18, 1942, by Near's Food Co., Inc., and the Troy Chemical Co., Inc., from Binghamton, N. Y.

Analysis showed that the article consisted essentially of hexamethylenetetramine, manganese, cobalt, copper, iron, sodium, potassium and magnesium salts including iodides, sulfates, and chlorides, together with sulfur and plant material.

The article was alleged to be misbranded in that the representation that the article was a preventive and appropriate treatment for mastitis was false and misleading, since the article was not a preventive or appropriate treatment for mastitis.

On August 28, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

847. Misbranding of Apcoton and Apco Worm-Tabs. U. S. v. 21 Packages of Apcoton and 33 Bottles of Apco Worm-Tabs. Default decree of condemnation and destruction. (F. D. C. No. 7961. Sample Nos. 11385–E, 11387–E.)

In addition to false and misleading curative and therapeutic claims in the labeling of both of these products the "Apcoton" contained a smaller amount of nicotine alkaloid than declared, and the Apco Worm-Tabs contained smaller amounts of nicotine and copper sulfate than declared.

On July 29, 1942, the United States attorney for the Southern District of Texas filed a libel against 21 packages of Apcoton and 33 bottles of Apco Worm-Tabs at Houston, Texas, alleging that the articles had been shipped in interstate commerce on or about June 13, 1942, by the American Products Co., Inc., from Shawnee, Kans.

Analysis of a sample of the Apcoton showed that it contained iron sulfate, copper sulfate, nicotine 0.5 per cent, talc, and plant material, including capsicum. It was alleged to be misbranded in that the statements on the labeling: "Flock Treatment * * * As tonic—stomachic * * * As a Flock treatment * * * Contains * * * (Nicotine Alkaloid, 6%)," were false and misleading since they represented that the article was a flock treatment for diseased conditions of poultry and was an effective tonic and stomachic for poultry, whereas it was not so effective and it failed to contain the quantity of nicotine alkaloid declared.

Analysis of a sample of the Apco Worm-Tabs shows that it consisted of iron oxide coated tablets, containing essentially kamala, nicotine 0.163 grain, copper sulfate 1.89 grains, with small amounts of napthalene and nux vomica. It was alleged to be misbranded in that the statements: "For combatting infestation of large round worms (Ascaris) and large tape worms (Infundibuliformis) in poultry. Contains * * * Nicotine 1.4 gr., copper sulphate 2½ gr." were false and misleading, since the article did not contain sufficient amounts of any ingredient to be an effective treatment for any species of worms which infest poultry and did not contain the quantity of nicotine and copper sulfate declared.

On September 17, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

848. Misbranding of Korum. U. S. v. 38 Gallon Bottles, 22 ½-Gallon Bottles, 126 32-Ounce Bottles, 309 16-Ounce Bottles, and 36 8-Ounce Bottles of Korum and 500 copies of a circular entitled "Russell Poultry Medicines and Biologics." Default decree of condemnation and destruction. (F. D. C. No. 8013. Sample No. 4601–F.)

On August 1, 1942, the United States attorney for the Southern District of Ohio, filed a libel against the above-listed amounts of Korum, and accompanying circulars, at Lewisburg, Ohio, alleging that the product, Korum, had been transported in interstate commerce on or about June 8, 23, and 24, 1942, and that the copies of the circular had been transported in interstate commerce on or about June 15, 1942, both by I. D. Russell Co., from Kansas City, Mo.

Analysis of the sample of the Korum showed that it consisted essentially of sodium chloride, potassium dichromate, small proportions of sodium chlorate, potassium nitrate, Epsom salt, and water.

It was alleged to be misbranded in that certain statements appearing in the booklet accompanying the article which represented and suggested that it constituted an effective preventive and treatment for coccidiosis, mycosis, and respiratory diseases of poultry, when used as directed, were false and misleading since it would not constitute an effective preventive or treatment for such conditions.

On September 15, 1942, no claimant having appeared, judgment of condemnation was entered and the drug and circulars were ordered destroyed.

849. Misbranding of Wormo. U. S. v. 21⅝ Dozen Bottles and 4 11/12 Dozen Bottles of Wormo. Default decree of condemnation and destruction. (F. D. C. No. 7855. Sample No. 70569–E.)

On or about July 14, 1942, the United States attorney for the Southern District of Florida, filed a libel against 21⅝ dozen 3-ounce bottles and 4 11/12 dozen 6-ounce bottles of Wormo at Worthington Springs, Fla., alleging that the article had been shipped in interstate commerce on or about January 26, 1942, by Blaco Chemical Co., from Robstown, Tex.

Analysis showed that it consisted essentially of chloroform, coal tar, cresols, soap, and water.

The article was alleged to be misbranded in that certain statements on the bottle label and in an accompanying circular, which represented and suggested that it would be efficacious for the treatment, relief, and expulsion of internal parasites in poultry, and in dogs, cattle, sheep, swine, and, horses; and would be efficacious in the treatment of colic and bots in horses, stomach and intestinal worms in sheep, hogs, and dogs, and running fits in dogs, were false and misleading since it would not be efficacious for such purposes. It was alleged to be misbranded further in that the declaration of the name and quantity or proportion of chloroform and the designation of the active ingredients of the article, required to appear in the labeling were not prominently placed thereon with such conspicuousness (as compared with other words in the labeling) as to render them likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

On August 6, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

850. Misbranding of Knox-It. U. S. v. 20 Packages and 72 Packages of Knox-It. Default decree of condemnation and destruction. (F. D. C. No. 6825. Sample No. 74195–E.)

On February 6, 1942, the United States attorney for the District of New Jersey filed a libel against 92 packages of Knox-It at Little Falls and Upper Montclair, N. J., alleging that the article had been shipped in interstate commerce on or about January 16, 1942, by the Syracuse Pharmacal Co., Inc., from Syracuse, N. Y.

Analysis of a sample of the article showed that it consisted essentially of plant material including a cereal, iodoform, methenamine, sulfur, lime, small proportions of a copper compound, and an iodide.

The article was alleged to be misbranded in that statements in the labeling which represented that it was an appropriate treatment for common disturbances of the mammary system of cattle, or garget, which result in thick, bloody, stringy milk and that it was a suitable preventive of garget were false and misleading since it would not be efficacious for such purposes.

On July 7, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

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PRODUCTS

SHIPPERS AND MANUFACTURERS

[1] Seizure contested; contains findings of fact and conclusions of law.
[2] Prosecution contested.
[3] Permanent injunction issued; contains court opinions.

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